DEFICIENCIES IN ADMINISTRATION OF FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE COMMITTEE ON GOVERNMENT OPERATIONS HOUSE OF REPRESENTATIVES

NINETY-FIRST CONGRESS

FIRST SESSION

MAY 7 AND JUNE 24, 1969

Printed for the use of the Committee on Government Operations

U.S. GOVERNMENT PRINTING OFFICE
33-145 WASHINGTON : 1969

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DEFICIENCIES IN ADMINISTRATION OF FEDERAL INSECTICIDE, FUNGICIDES, AND RODENTICIDE ACT

WEDNESDAY, MAY 7, 1969

HOUSE OF REPRESENTATIVES,
INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, D.C.

The subcommittee reconvened at 10 a.m., in room 2247, Rayburn Building, the Honorable L. H. Fountain presiding.

Present: Representatives John C. Culver, Benjamin S. Rosenthal, Florence P. Dwyer, Clarence J. Brown, and Guy Vander Jagt.

Also present: James R. Naughton, subcommittee counsel, and William H. Copenhaver, minority counsel.

Mr. FOUNTAIN. Let the committee come to order and the record show that a quorum is present.

Under the rules of the House, the Committee on Government Operations has responsibility for examining the operation of Government activities at all levels with respect to economy and efficiency. The committee also has responsibility for receiving and examining reports of the Comptroller General and submitting such recommendations to the House as it deems necessary or desirable in connection with the subject matter of such reports.

These responsibilities insofar as they relate to the Department of Agriculture and certain other departments and agencies have been assigned by the committee to the Intergovernmental Relations Subcommittee.

The subcommittee hearing today will be concerned with the administration by the Department of Agriculture of the Federal Insecticide, Fungicide, and Rodenticide Act. We are particularly interested in ascertaining the action being taken or planned by the Department to correct deficiencies cited in the two recent General Accounting Office reports concerning the Department of Agriculture's administration of the act.

We have with us this morning to testify Dr. Robert J. Anderson, Associate Administrator of the Agricultural Research Service of the Department, and Dr. Anderson, I understand you have with you Dr. Bayley, Director of Science and Education; Dr. Francis J. Mulhern, Deputy Administrator of the Regulatory and Control Programs; and Dr. Harry W. Hays, Director of the Pesticides Regulation Division; and Mr. Lowell E. Miller, Assistant Director for Enforcement, Pesticides Regulation Division to supplement you or to be available for questions by members of the committee.

We are delighted to have you with us this morning. Before you begin your statement, I would like to say for the benefit of the members of the committee, I will try to develop what has happened in as orderly a fashion as I can and I will try to stop for an occasional point to give the members of the committee an opportunity to ask any questions they may like, but if you have something that you think ought to be answered right at the point where I am asking questions, don't hesitate to interrupt for the benefit of the record.

Dr. Anderson, I believe you have a prepared statement along with some documentary information which will become a part of the record along with your statement.

You may proceed.

STATEMENT OF DR. ROBERT J. ANDERSON, ASSOCIATE ADMINISTRATOR, AGRICULTURAL RESEARCH SERVICE, U.S. DEPARTMENT OF AGRICULTURE

Dr. ANDERSON. Thank you, Mr. Chairman. As you indicated, I have with me this morning Dr. Ned D. Bayley to my left here who is Director of Science and Education in the Office of the Secretary; Dr. Harry Hays, the Director of the Pesticides Regulation Division; Mr. Lowell E. Miller, Assistant Director for Enforcement, Pesticides Regulation; and Dr. Francis Mulhern, who is Deputy Administrator of the Regulatory and Control Programs.

I am the Associate Administrator of the Agricultural Research Service, having served many years in the regulatory and control activities of plant and animal diseases, and I was formerly Deputy Administrator for the Regulatory and Control Program.

I am pleased to be here this morning to report to you on recent actions taken by the Agricultural Research Service in two areas of our responsibility: (1) Improving regulatory enforcement procedures involving pesticides, and (2) resolving questions of safety concerning certain registered uses of lindane pesticide pellets.

Activities in these areas are administered by ARS according to the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Outlines of our structure and staffing to administer FIFRA, and our requests for funds to expand the enforcement program in fiscal year 1970, are attached to my statement.

The first Insecticide Act was passed by the Congress in 1910, primarily to protect farmers against adulterated or misbranded materials. The act was replaced and expanded in 1947 by the FIFRA.

The current legislation, amended in 1959 and in 1962, is based on the concept of protecting the public and our total environment from possible hazards created by the use of economic poisons. Registration procedures require proof of the safety and effectiveness of a material before it is marketed in interstate commerce.

Procedures also require specific label directions and any warnings that may be necessary for the safe use of the product.

The act covers a wide variety of over 45,000 products including, in addition to the originally defined pesticides and disinfectants, such materials as nematocides, plant growth regulators, defoliants, desiccants, and all products used to control or repel pest birds, predatory animals, reptiles, rough fish, plant diseases, and weeds.

Methods of enforcing the act and the safety involved in registered uses of lindane pesticide pellets were called to the special attention of the Congress by two reports from the Comptroller General of the United States. The reports were dated September 10, 1968, and February 20, 1969.

The Department of Agriculture was given an opportunity to review the reports in draft form, and our replies to the U.S. General Accounting Office are included as part of both finished documents.

The Department's comments are contained in letters addressed to Mr. Victor L. Lowe, of GAO, over my signature as Acting Administrator of the Agricultural Research Service and dated May 22, 1968; and to Mr. A. T. Samuelson, of GAO, over the signature of Dr. Ned D. Bayley as Director of Science and Education and dated November 27, 1968.

I would like to request permission for these two letters to be placed into the record at this point.

Mr. FOUNTAIN. With no objection, they will be admitted in the record.

(The letters referred to appear in the appendix on pp. 173 and 214.)

The correspondence accurately reflects our position and plans at the time the reports were made to the Congress. I would like now to bring our position up to date.

The findings of the GAO report on the "Need To Improve Regulatory Enforcement Procedures Involving Pesticides" included these two important points: (1) Enforcement actions may not have removed misbranded, adulterated, or unregistered products from the market; and (2) repeated violators of the FIFRA have not been prosecuted.

In removing violative products from the market, we believe that recalls by the manufacturer or shipper are the most effective and efficient means. In applying recall procedures, the Agricultural Research Service requests that the industry member involved voluntarily recall from the market a product found to be potentially hazardous or seriously ineffective.

Although the FIFRA contains no provisions relating to the recall of products, the voluntary action is proving to be highly effective. In September 1967, ARS made its first request to a manufacturer that a complete recall of a product be initiated. Since that time, the recall system has become an integral part of our enforcement system and definitive procedures from the Pesticides Regulation Division, 905.002, "Recall of Products," is attached to my statement.

During the first 10 months of fiscal year 1969, 32 formal recall actions have been initiated at the request of ARS. We believe our recall program has been an effective means of removing violative products from the market.

To the extent that recall actions are effective, there will be no necessity to resort to seizure actions. An important aspect of our seizure activities in the future will be directed toward the removal from the market of potentially hazardous or ineffective products when recall action is not effective.

This involves (1) obtaining from the manufacturer or shipper information concerning all consignees of the violative product; (2) obtaining samples of such product at every possible product location;

and (3) initiating seizure actions with respect to such product in every instance when supporting data is obtained.

We are now in a much stronger position to insure the removal of potentially hazardous products from the market.

In our efforts to strengthen the prosecution of violations of the act, ARS created a new prosecution and import section in December 1967. The purpose in creating this section was not only to establish more effective procedures for the handling of prosecutions, but also to focus attention upon the fact that prosecutions are an important part of the enforcement program.

When we believe criminal prosecution is necessary, a file is prepared in the prosecution and import section and the matter is referred to the Office of the General Counsel of the Department, with a recommendation that prosecution be started.

Present guidelines of ARS for referring cases to the Office of the General Counsel are as follows: (1) The evidence indicates that the violation was willful, (2) the violation is of a serious nature and is the result of apparent gross negligence, or (3) the company has engaged in repeated violations.

In line with these criteria, we are now putting major emphasis on starting action against repeated violators. On March 27, 1969, a grand jury in Chicago returned an indictment against a company and four of its officers. Two additional files have been forwarded to the Office of the General Counsel with recommendation for criminal action. At the present time, files relating to alleged violations of the act by approximately 20 companies are in various stages of preparation.

We recognize the need for greater effort throughout all our enforcement activities if we are to provide proper protection for the public in line with the intent of the act.

We are strengthening our staff whenever and wherever possible within recognized limitations of budget and personnel ceilings. Within the last 2 months we have added six people to the Case Review and Development Section, concerned with reviewing all reports from our laboratories analyzing the products from the field that have been sampled and tested.

We are continuing to strengthen procedures for registration. We are evaluating these procedures and upgrading requirements whenever necessary to make sure that registered products are effective and safe when used according to directions.

Our approach to the registration of disinfectants is one example of this effort. We are requiring data on pilot studies made on much larger batches than the test-tube amounts formerly accepted, presented in three samples instead of one. As a result, we are now asking for data on the product as it will be marketed.

This is part of our concern with new chemicals used as disinfectants—both as to safety and to their effectiveness. In safety precautions, we are particularly concerned about effects upon young children and older people as the most susceptible segments of our population.

The remainder of my statement deals with factors involved in the second GAO report to Congress entitled "Need To Resolve Questions of Policy Involving Certain Registered Uses of Lindane Pellets."

Our position on registered uses of lindane pellets at the time was

presented in the letter of November 27, 1968, signed by Dr. Ned D. Bayley, and previously inserted in this record.

Since then, the Agricultural Research Service has taken the following actions in an effort to resolve the problem associated with the use of lindane pellets: (1) arranged a meeting with the medical authorities who serve as collaborators to the Pesticides Regulation Division, (2) conducted a study to determine whether lindane would be deposited on foods and dishes as a result of the operation of a lindane vaporizer, (3) arranged a meeting with representatives of member agencies of the interdepartmental agreement, and (4) notified manufacturers that registration of lindane products for use in vaporizing devices is canceled, effective 30 days following receipt of the notice dated April 24, 1969.

Our medical advisers met in New York City, January 7, 1969, to consider information on lindane provided for them. On the basis of this information and additional data on studies with lindane, the collaborators presented a report to ARS concluding that hazards associated with lindane pellets used in vaporizers constitute an undue risk to the health of those who may be continuously exposed to the vapors.

In February 1969, scientists of the Pesticides Regulation Division conducted an experiment at the Agricultural Research Center, under simulated restaurant conditions, to determine whether the use of lindane vaporizers would result in contamination of food. By the end of 5 days' exposure, practically all foods, packaged and unpackaged, contained illegal residues of lindane.

In the meantime, problems involving lindane pellet registration needed further attention. The Department of Agriculture arranged for a meeting of representative members of the interdepartmental agreement on March 19, 1969.

The agreement, adopted in February 1964, outlines methods of cooperation on matters pertaining to pesticides by representatives of three Federal Departments—Agriculture, Interior, and Health, Education, and Welfare. At the March 19 conference, it was decided to hold periodic meetings of a working group from the three Departments to resolve any continuing differences.

We then reviewed the information provided by the medical advisers, results of the test for food contamination by lindane vaporizers, and the exchange of views with representatives of the interdepartmental agreement.

On the basis of these facts—including the evidence of residues in food when no tolerance is set for lindane by the Food and Drug Administration—we took action to cancel the registration of lindane products for use in vaporizing devices.

That concludes my statement. We will be glad to answer your questions at this time.

Mr. FOUNTAIN. Thank you, Doctor. For the record would you give us a brief outline of your background, training, and experience and then the others, when and as they may answer questions, can do the same thing.

Dr. ANDERSON. I received a degree in veterinary medicine at Texas A. & M. University in 1935 and went to work for the Bureau of Animal Industry the same year and livestock disease control work and I

am approaching my 34th year of service with the Federal Government. I served in Mexico on foot and mouth disease work, and came up to where in 1961 I became Assistant Deputy Administrator for Regulatory and Control Programs which was responsible for the five regulatory divisions of the Agricultural Research Service. In 1963 I became the Deputy Administrator and I served in this position until 1966. Since 1966 I have been Associate Administrator of the Agricultural Research Service, which conducts research as well as administers regulatory programs.

Mr. FOUNTAIN. Thank you. Right at the outset I might ask what might be described as a summarizing question before we proceed with the questioning.

Do you find any fault with the September 10, 1968, and February 20, 1969, reports of the Comptroller General?

Dr. ANDERSON. No, sir. On the contrary, we found these reports to be very helpful to us in carrying out our responsibility in administering the act.

Mr. FOUNTAIN. So you are in the process of trying to comply with the recommendations which they make in that report?

Dr. ANDERSON. Yes, sir.

Mr. FOUNTAIN. I have a number of questions I would like to ask. If any question I ask you might be more appropriately answered by one of your colleagues, I hope they will feel free to go ahead and supplement or reply to the question.

If there is no objection, the two General Accounting Office reports which we will be discussing today will be made a part of the committee hearing record.

(The reports referred to appear in the appendix on pp. 141 and 181.)

I think it would also be helpful to include in the record the supplemental material submitted to the subcommittee by the Department of Agriculture for the hearing. In this connection, where detailed information has been supplied for the record that may be responsive to a question, it would be helpful if the witness would so indicate and eliminate unnecessary details from his answer insofar as feasible.

(The supplemental material referred to appears in the appendix on p. 241.)

Mr. FOUNTAIN. Dr. Hays, I note that you approved the memorandum attached to Dr. Anderson's statement which sets forth the procedures for recall of products. When did you approve it?

Dr. HAYS. April the 25th, I believe.

Mr. NAUGHTON. Excuse me, Dr. Hays, that is the date that the memorandum bears. I assume it was sent to you for approval at that time. Do you recall the date that you actually affixed your signature to it approving it?

Dr. HAYS. May the 5th.

Mr. NAUGHTON. That would be Monday of this week then?

Dr. HAYS. Yes.

Mr. FOUNTAIN. Do you recall when the GAO review of your enforcement procedures began?

Dr. HAYS. As I recall, they began about October or November of 1966.

Mr. FOUNTAIN. Doctor, before proceeding further, I wonder if you would give us for the record a brief statement of your background of training and experience.

Dr. HAYS. I was a graduate of Franklin Marshall College with a B.S. degree in 1933, a master of science degree from Princeton University in 1937, doctor of philosophy degree in 1938 from Princeton University. I was assistant to the director of research for the Ciba Pharmaceutical Co. in Summit, N.J., from 1938 to 1948. I was associate professor of pharmacology at Wayne State University College of Medicine in Detroit from 1948 to 1957. I was Director of the Advisory Center on Toxicology for the National Academy of Sciences, National Research Council, Washington, D.C. from 1957 to 1966, and from 1966 to the present time, Director of the Pesticide Regulation Division, Agricultural Research Service.

Mr. FOUNTAIN. Before asking you for that information I believe I asked you when the GAO started its review of your enforcement procedures and you replied in October of 1966?

Dr. HAYS. I think the latter part of 1966.

Mr. FOUNTAIN. We have information indicating May or June of 1967. I just want to correct that for the record.

Dr. HAYS. It was shortly after I came to the Division.

Mr. FOUNTAIN. Then this was a preliminary investigation before the actual investigation and full investigation started?

Dr. HAYS. Yes.

Mr. FOUNTAIN. According to the statement, the first request by the Agricultural Research Service for recall procedures was made in September 1967. Does that mean that until September of 1967 no use whatsoever was made of the recall procedure?

Dr. HAYS. That is correct.

Mr. FOUNTAIN. In other words, during the 20 years from 1947 when the Federal Insecticide Act became law to September of 1967, no use was made of the recall procedure?

Dr. HAYS. As far as I am aware, no.

Mr. FOUNTAIN. And even though it is your own belief according to your statement, Dr. Anderson, that the recall procedure is "the most effective and efficient means" for removing from the market products which violate the act, no action had been taken to recall any of these products?

Dr. ANDERSON. No, sir; this is based on the lack of authority in the act providing for the recall action.

Mr. FOUNTAIN. Now, you have put into effect recall procedure?

Dr. ANDERSON. It is a voluntary recall procedure that is working quite well.

Mr. FOUNTAIN. You do have seizure authority?

Dr. ANDERSON. Yes.

Mr. NAUGHTON. Doctor, you have no more specific legal authority for recall action now than you had 20 years ago when the act was passed?

Dr. ANDERSON. No, sir; that is correct. This is part of our redirection of enforcement activities. We believe it is a step in the right direction.

Mr. NAUGHTON. So you really cannot blame deficiencies in the law for the 20-year void in recall procedures?

Dr. ANDERSON. No.

Mr. FOUNTAIN. I wonder if you could explain to the committee just why it took the Department this long or why nothing had been done in terms of recall procedures prior to September 1967?

Dr. ANDERSON. Mr. Chairman, unfortunately, those that were in control during all that time are not present here this morning.

Mr. FOUNTAIN. I understand that and I understand all of you are not responsible for everything.

Dr. ANDERSON. We had relied quite heavily upon the citation provision of the act to bring about corrective means or compliance with the act. It has proved very useful but we found through experience that it was not sufficient to bring about corrective action where it was absolutely necessary. In the absence of recall authority, we have had to rely upon our seizure authority to remove products that are in violation from the market. That is a rather cumbersome legal procedure as you can expect.

It requires multiple seizures wherever the product is found. It would not apply to a seizure that could be applied nationwide.

Mr. FOUNTAIN. Then are you saying that you probably overrelied upon the citation provisions of the law?

Dr. ANDERSON. Our experience has shown that the recall is a more effective method for removing products in violation of the law.

Mr. FOUNTAIN. Is it true that the Insecticide Act is patterned substantially after the Food, Drug, and Cosmetic Act, which is administered by the Food and Drug Administration?

Mr. ANDERSON. Basically, that is correct, sir.

Mr. FOUNTAIN. Do you know how long FDA has been using recall procedures?

Dr. ANDERSON. No, sir; I do not.

Mr. FOUNTAIN. Mr. Naughton, do you know?

Mr. NAUGHTON. No, I do not. Is there a gentleman from FDA here who could give us that information?

Dr. ANDERSON. Les Ramsey of the Food and Drug Administration was here.

Mr. FOUNTAIN. Mr. Ramsey, could you, by chance, tell us on what date FDA started using recall procedures?

Mr. RAMSEY. I am sorry, I do not have the information.

Mr. NAUGHTON. Do you know approximately? Has it been more than 10 years ago?

Mr. RAMSEY. I would say so, yes. I can supply the information.

(The Food and Drug Administration subsequently advised the subcommittee that FDA has been using recall procedures since at least 1937.)

Mr. FOUNTAIN. Thank you. I might add that FDA has no specific statutory authority for recall either.

What is your opinion, Doctor, as to the effectiveness of seizure as you utilized it in removing potentially harmful products from the marketplace?

Dr. ANDERSON. Mr. Chairman, it was effective in removing those products found to be in violation of the act. Experience has shown it is not as effective as the recall action in removing them. You can understand that is the reason we are placing greater emphasis on the recall procedure than the former reliance placed on seizure as a means of removing them from the marketplace.

Mr. FOUNTAIN. When your inspectors found a potentially harmful product in a retail establishment, did you, in addition to seizing the product of that particular establishment, customarily examine the manufacturer's records to ascertain how many other interstate shipments of similar products had been made and where they were located so you could seize them?

Mr. MILLER. Mr. Chairman, do you want a brief biographical sketch?

Mr. FOUNTAIN. Yes.

Mr. MILLER. My name is Lowell Miller. I graduated from the University of Iowa Law School in 1948. Following passage of the Iowa bar, I accepted a position with the Office of the General Counsel, USDA, in November of 1948. For the first couple of years I did work for the Rural Electrification Administration; following that, my work in the General Counsel's office was related to a wide variety of regulatory statutes. During the last 10 years or so that I was in OGC my work was primarily that of trial attorney under the Packers and Stockyards Act, trade regulation work. I was also responsible for the legal work under the Federal Insecticide, Fungicide, and Rodenticide Act.

In February of 1963 I transferred to the trial staff of the Federal Trade Commission and I was on the trial staff of the Federal Trade Commission until May of 1967 when I accepted my present position as Assistant Director for Enforcement, Pesticide Regulation Division, ARS.

Mr. FOUNTAIN. What year was that when you came?

Mr. MILLER. May 1967.

Mr. FOUNTAIN. Now, you may proceed to answer the question.

Mr. MILLER. I believe your question, Mr. Chairman, was did we, customarily, when a lot of a violative product was sampled, go to the records of the company to obtain product location data?

Mr. FOUNTAIN. Right.

Mr. MILLER. You are referring to past activities——

Mr. FOUNTAIN. Yes.

Mr. MILLER. The answer is "No." It was not ordinarily done; no, sir.

Mr. FOUNTAIN. Was it ever done that you know of?

Mr. MILLER. Not that I am aware of at least on a routine basis.

Mr. FOUNTAIN. Does anybody else know whether that was ever done?

Dr. ANDERSON. I believe your question, too, sir, was centered around a hazardous product.

Mr. FOUNTAIN. Potentially harmful.

Dr. ANDERSON. Do we have any information on a case of that kind, Mr. Miller?

Mr. MILLER. Yes, there have been instances. I am trying to recall some specific instances where, on a potentially hazardous product, efforts would have been made to obtain data concerning more than one product location. But I will have to say it was not done on a regular basis.

Mr. FOUNTAIN. In any event, if seizure was made of a product in one location and no effort was made to ascertain other locations where the product might be found—and they might be found in countless places—the seizure would be effective only with respect to that par-

ticular location and the same product would continue to be sold at all of the other locations?

Dr. ANDERSON. We would be glad to search our records and submit for the record, Mr. Chairman, any information we have on that subject.

Mr. FOUNTAIN. All right.

(The information referred to follows:)

The Department of Agriculture subsequently reported that it had located two instances in which multiple seizures had been made prior to 1967, one in 1962 and the other in 1963.

The 1962 seizures involved a product called Steri-Fleece, manufactured by Calusa Chemical Co., Inc., Los Angeles. Seizure actions were taken at four locations and resulted in a total of one 150-pound, five 100-pound and 14 50-pound drums of the product being removed from the market. Although copies of certain shipping records were obtained from the manufacturer, USDA did not know whether the amounts seized represented all quantities of the violative product being marketed.

In 1963, a total of three 30-gallon, 135 5-gallon and 61 1-gallon containers of E-Z-Flo Dairy and Livestock Spray were seized from eight different locations. This product was manufactured by the Stauffer Chemical Co., New York City; however, Stauffer Co. records were not examined.

Mr. BROWN. Mr. Chairman, may I ask a question at this point?

Mr. FOUNTAIN. Yes.

Mr. BROWN. Do you also have any record as to whether or not the Agriculture Department had been in a position of actively advocating the use of products which an agency of the Department has seized?

Dr. ANDERSON. Mr. Congressman, the Agriculture Research Service has—or the Department has two basic functions; one of conducting research and recommending pest control practices—effective pest control practices to the farmer. This involves many chemicals, many formulations, and many types of pest controls. We also have the responsibility for the registration of the Federal Insecticide, Fungicide, and Rodenticide Act. These two activities are totally unrelated and the recommendation of the Department is not tied in with the act except that the recommendation must be a registered use with this agency.

So, to answer your question, I am not aware of any product that was involved. It could have been but it is not a case of us sponsoring a product, per se. We have no interest whatever in any particular product. If it is safe and effective, the Department will recommend it as a pest control measure. If it is not, it will be the first to remove it from its list of recommendations along with the cancellation procedures of the Pesticide Regulation Division.

Mr. BROWN. Could I pursue that just a moment, please?

Mr. FOUNTAIN. Yes.

Mr. BROWN. My question is whether the Agricultural Research Service, as the branch of the Department of Agriculture which is charged with the checking of products as to their safety and efficacy, when it finds a product which is disapproved, notifies any other branch of the Department of Agriculture which might be in the process of encouraging or advocating the use of the product by farmers or rose growers or whatever it might be?

Dr. ANDERSON. Yes, sir, very much so. We work very closely in the registration branch of the division and with extension people, and our research people when registered uses are canceled. There was the case of heptachlor and dieldrin used on certain crops such as alfalfa which would result in illegal residues in the milk. We im-

mediately notified the Extension Service. They got word out to all the agents. We put out press releases. So, we used all of the available news media to inform the farming community of these changes in registration.

We will be glad to give a description of the action, for the record, to show steps taken by the Department to inform the public.

(The following statement was subsequently supplied:)

TYPE OF ACTION TO INFORM THE PUBLIC AND FARMING COMMUNITY OF CHANGES IN REGISTRATION

When it is necessary to cancel or amend certain registered uses, the registrant is advised of such action as required by the act. A notice is prepared and distributed to all registrants as well as State regulatory agencies announcing the nature of the action. This is accompanied by a press release prepared by the Information Division.

If the use pattern involves food or feed crops as listed in the "USDA Summary of Registered Agricultural Pesticide Chemical Uses," an amendment to reflect the change is prepared and distributed to all holders of the summary. This information is made available immediately to the FES and others concerned with the recommendation and use of pesticides.

Mr. BROWN. Maybe we can pursue that when we get to more specific products.

Mrs. DWYER. Dr. Anderson, aside from the testing of products, seeking registration, what actual criteria does ARS use to test products already on the market to determine whether they are misbranded, adulterated, or unregistered? Who do you depend on for this information?

Dr. ANDERSON. We have a series of laboratories of our own located at different points in the United States. The laboratories test and analyze samples collected by their field inspectors. I will be glad for Dr. Hays to comment on that further, if you wish.

Mrs. DWYER. Yes, I would like to have him do that.

Dr. HAYS. We have five analytical chemical laboratories to which these samples are submitted for chemical analysis. The results of their analysis are then referred to the Washington office for review. We have also six biological laboratories in entomology, plant biology, bacteriology, pharmacology, and toxicology. Many of these products are referred to these biological laboratories for testing to see whether, in fact, the product is effective when used in accordance with the directions.

Mrs. DWYER. Do you coordinate your work with the Public Health Service and the Food and Drug Administration; and have you any general coordination or communication arrangement relating to the work you do?

Dr. ANDERSON. We have the interdepartmental coordinating agreement, Mrs. Dwyer, which was entered into between the Department of HEW, Agriculture, and Interior. This agreement provides for USDA to forward all applications for registration to HEW and to the Department of Interior for their advice and recommendation relative to hazards, if any, to fish and wildlife and for human health problems.

Their advice and recommendations are considered and weighted carefully in connection with the decision to register or refuse registration of a product.

Mrs. DWYER. What about the case of lindane, for instance?

Dr. ANDERSON. Lindane was originally registered in the early 50's

with the concurrence of HEW. This was based on the data submitted by the registrant pertaining to safety.

Later there were some misgivings about this registered use in which they concurred. We took the position that if we could obtain additional data that would support the misgivings, we would act immediately. But the data supplied with the application for registration and the basis for their original concurrence seemed to have been adequate at that time and no new information became available that would warrant our changing the registration.

Mrs. DWYER. Have you changed your opinion now?

Dr. ANDERSON. We have, yes, ma'am.

Mrs. DWYER. After these hearings were announced or before?

Dr. ANDERSON. We have already taken action on this product, as we mentioned earlier, to cancel the registered use. This was based on several actions.

First, with some additional information published in 1967 showed that lindane residue would accumulate in tissues of animals exposed to vapors. Also, some additional studies showed that people suffering from malnutrition would be more susceptible to the toxic effects of lindane.

Also, we conducted some experimentation of our own at our Beltsville Research Center under simulated restaurant conditions. In these tests we found that the registered use would result in the presence of illegal residue on food, on cooking utensils and meat preparation counters. We made the determination that the direction for use was not adequate to prevent the illegal residue. There is no tolerance for lindane residues associated with the use. Therefore, it would be in violation of the act. In a combination, this information was the basis for our moving against the lindane vaporizing pellets.

Mrs. DWYER. Didn't you have this information 2 years ago, Dr. Anderson?

Dr. ANDERSON. No.

Mrs. DWYER. I thought you said 1967.

Dr. ANDERSON. Part of the information in the journals was available at that time but tests simulating the restaurant conditions were conducted in February of this year. This showed that contamination was occurring.

Mrs. DWYER. Thank you, Mr. Chairman.

Mr. FOUNTAIN. I notice, Doctor, the 1966 Agriculture Yearbook contains an article prepared by ARS describing enforcement of the act, and on page 279 this statement is made, and I quote:

> That aggressive enforcement action to take dangerous pesticides off the market has been a significant part of the protection being given the public.

I guess if you had it to do over again you probably would not characterize what you were doing in 1966 as aggressive enforcement action.

Dr. ANDERSON. As compared to the action we are taking today, I would say it is a rather poor choice of words.

Mr. NAUGHTON. To get this straight, in 1966 and prior thereto, is it correct that your normal procedure when your inspectors found a sample of a product which was in violation of the act and which might be dangerous and potentially harmful in a retail establishment, the procedure followed was to seize the product in that particular

retail establishment and if this was one of 50,000 retail establishments which had received that potentially harmful product it would be seized at one establishment and remain for sale without interference by ARS in 49,999 other establishments? Is that accurate?

Dr. ANDERSON. I believe I answered the chairman. We would have to check to see how many multiple seizures that we did initiate where there was evidence of a hazardous product on the market. We do not recall any here, but we will check it.

(The information referred to appears on p. 10.)

Mr. NAUGHTON. We have the assembled heirarchy of the Agricultural Research Division here, the experts in this field, and not one of you, if I am correct, can recall a single instance in 20 years from 1947 to 1967 in which you went to the records of the manufacturer to establish where other supplies of a dangerous product, potentially harmful product, was so that you could seize it?

Dr. ANDERSON. We would have to first assume that testing did reveal a hazardous product on the market.

Mr. NAUGHTON. Well, a product in violation, whether it was hazardous or ineffective. My question is, can any of you at this table recall a single instance in 20 years where you went to the records of the manufacturer to find out where additional supplies of that product were located for sale so that you could take it off the market completely rather than simply at one retail establishment?

Dr. ANDERSON. We do not recall any instance where we went directly to the records of the company. Whether we made multiple seizures in this connection, I cannot say.

Mr. NAUGHTON. You are familiar with the findings of GAO as to 1966?

Dr. ANDERSON. Yes.

Mr. NAUGHTON. And they found you made 106 seizure actions in fiscal 1966 and that 22 of those seizure actions resulted in no product being seized because it had either been sold or disposed of by the time your seizure became effective, and the other 84 involved 79 different products at only 80 different locations. Isn't this a clear indication that in 1966 you were seizing only at the one establishment where you found a violative sample?

Dr. ANDERSON. Yes, sir. If I may, Mr. Chairman, comment on this. In 1965, the Department was really concerned about the administration of our Federal Insecticide and Rodenticide Act. The Secretary established a task force to look at the organization and the activities of the Pesticide Regulation Division to determine if it was adequately organized and properly functioning to adequately administer the act. This task force was headed by Dr. Hays. It made many recommendations, some of which were contained in GAO reports from similar recommendations. It was at that time we began our efforts in taking action to strengthen the Department's administration of the act. We admit that there were deficiencies in the way it was administered. Not the act, but the way it had been administered over the years. But, presently we believe that we have a program under which that will bring about effective administration.

Mr. NAUGHTON. Doctor, I am sure your statement indicates some significant improvements that are being made.

Can you think of any significant improvements which were initiated prior to the time the GAO began its study in 1966 or 1967?

Dr. ANDERSON. Yes, sir. It deals with the total division activities. Following this task force report, we brought aboard a new director who is Dr. Hays. We reorganized the division, giving greater emphasis to criteria of safety used in the registration process. We set about reorganizing field forces. We requested additional funds to add to our inspection staff in the field and all of these were in the period of development at the time of the GAO report. But, the report has been effective in helping us.

Mr. BROWN. Would you yield on that point?

Mr. NAUGHTON. Yes.

Mr. BROWN. How much money was being spent annually up to 1967 by the ARS? What was their budget for operations?

Dr. ANDERSON. I don't have it for 1967.

Mr. BROWN. I want to know before the recall procedures were instituted.

Mr. ANDERSON. 1968 is the latest we have available right here, Mr. Congressman. We would be glad to furnish it for the record. We have gotten increases somewhere in the neighborhood of $400,000 to $500,000 a fiscal year during this period.

(The information furnished follows:)

U.S. DEPARTMENT OF AGRICULTURE—AGRICULTURAL RESEARCH SERVICE

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Fiscal year:	*Funds available*
1953	$580,500
1954	587,600
1955	508,000
1956	617,000
1957	617,000
1958	659,300
1959	757,400
1960	1,012,600
1961	1,166,300
1962	1,166,300
1963	1,364,000
1964	1,479,600
1965	2,564,900
1966	2,621,100
1967	3,284,400
1968	3,644,900
1969 (estimated)	3,806,100

Mr. BROWN. What is it for 1968? I am curious to get in the realm of what figure was being spent by this agency.

Dr. ANDERSON. About $3 million in 1968, and 1967.

Mr. BROWN. In previous years it ran around $3 million, previous to 1967?

Dr. ANDERSON. In 1964 and 1965 we did get some increases which were used for two purposes. We have added 11 inspectors in the field force and we have strengthened our registration activities to take care of the tremendous backlog that we had there.

Mr. NAUGHTON. Doctor Hays' study was made, I understand, in 1965?

Dr. ANDERSON. Yes, sir.

Mr. NAUGHTON. And as of the end of 1966 you did not have any procedures in effect, did you, which notified your inspectors that if a dangerous product or a harmful product were found or a potentially violative product, that multiple seizures should be undertaken or they should go to the records to find out. Weren't their instructions simply to seize the products where they found them?

Dr. ANDERSON. That is correct, sir.

Mr. FOUNTAIN. In your statement, Doctor, you indicate that 32 formal recall actions were initiated during the first 10 months of fiscal year 1969. I wonder if you would give us some details as to the nature and the amount of products from the market through these recall actions? I think you can give us a brief description at this point with full details for the record but I would like for you to give some details on the more significant ones.

Dr. ANDERSON. Mr. Miller has the data summarized.

Mr. FOUNTAIN. All right. If you have somebody else better prepared to do this—did you hear the question?

Mr. MILLER. Yes, sir. You want me to summarize several significant actions?

Mr. FOUNTAIN. Yes, and then supply for the record the details on all the recalls.

Mr. MILLER. All right. Our records are complete with respect to 22 of these recall actions. Our records show that more than 1,300 potential product locations were contacted or surveyed by the manufacturer as a result of these recall requests.

Now, these recall requests run all the way from a product of very limited distribution to a product of national distribution. We are very gratified by the results which we have achieved in both these areas.

In one recall situation we obtained samples of two different batches of a product which was detemined to be completely ineffective and we initiated formal recall procedures; that is, we made a formal request to the manufacturer to initiate recall procedures. Subsequent to that initial recall request, we obtained additional samples while the initial recall was going on. These additional samples showed, as I recall, that five additional batches of the product were likewise ineffective, so we at that time requested the manufacturer to make a complete recall of the product. I believe 846 product locations were contacted by the manufacturer and in excess of 17,000 pounds of the product were recalled.

In another situation our test of a product showed a disinfectant to be, in our opinion, ineffective, and the company was requested to recall not only the product which it manufactured under its own label but the same formulated product which it manufactured under labels for others.

The company immediately put a stop order on this product and contacted 84 of the direct consignees of the product. Our interim report shows that the product was returned or removed from approximately 50 product locations. This involved more than 6,000 cases of the product or, in terms of units, 76,950 units of the product.

To give you one example, sir, of a recall of a product of limited distribution, as compared to seizure actions, one of our inspectors came across a shipment or a lot of 25-percent parathion product which bore no warning or caution labeling whatsoever. This was a small lot of the

product. We requested the manufacturer to initiate recall procedures and, in connection with our normal supervision of the recall the supervisory inspector checked the records of the company, first of all, to determine whether or not there were any additional shipments, or could be any additional shipments, of the same type of product outstanding.

He determined that this was the only lot of the product in this category and he also, in addition to making a record check, made a physical inventory check of this company's products and found additional units of this product which were improperly labeled, which were taken out of channels of trade.

In connection with his record check it was also determined that this product was manufactured by another manufacturer. So we went to that manufacturer's records to determine whether or not additional lots could have been moved into channels of trade. Our findings were negative in this instance, also, from the standpoint of additional shipments. I mention that merely to give you an example of the thoroughness with which we are checking records and making physical inventories of products in connection with our recall procedures.

Mr. FOUNTAIN. Will you supply for the record details in connection with the recalls?

Mr. MILLER. Yes, sir.

(The information requested appears in the appendix on p. 245.)

Mr. FOUNTAIN. The fact that you established so many locations where the products to which you have referred were found is a pretty good indication of the complete ineffectiveness of your seizure procedures in the past, is it not?

Dr. ANDERSON. Yes.

Mr. NAUGHTON. Mr. Miller, how dangerous is parathion?

Mr. BROWN. And what is it used for?

Mr. MILLER. I believe Dr. Hays, as a toxicologist, can answer that question much better than I can.

Dr. HAYS. It is used in a variety of insect control problems. It is classified as a highly toxic material. It is what we commonly refer to as an organophosphate. Its principal action is to depress the cholinesterase level of the blood. In doing so, it exerts its cholingeric effects. It can be reversed by the use of an antidote. It is labeled as a highly toxic material with danger, skull and crossbones, poison, and all of the precautionary statements necessary to protect the user if it is used in accordance with the directions.

Mr. BROWN. Is it commonly used as a household insect repellant?

Dr. HAYS. It is for agricultural uses.

Mr. BROWN. On field crops?

Dr. HAYS. Yes. It is not registered for home use.

Mr. NAUGHTON. This could be fatal if someone got some that wasn't properly labeled and didn't follow directions?

Dr. HAYS. Yes.

Mr. BROWN. May I pursue the use of it? Have studies been made to determine whether there is a residual effect in the crop or in the soil through usage of the parathion?

Dr. HAYS. This is not one of our groups of persistent insecticides. It is one of the rapidly hydrolizing or degrading compounds. It has been studied on residues in soil, in crops, but as I said, it is not in that

category of the long persistent pesticides such as the chlorinated compounds.

Mr. BROWN. Does the package ordinarily contain instructions for application and limitations on use?

Dr. HAYS. Yes. When tolerances have been established for any particular crop for any compound it has directions for use, such as do not apply 30 days prior to harvest, or whatever it might be.

Mr. NAUGHTON. Some of the products, of course, which are registered are highly dangerous if misused or inhaled or if put on the skin, and so forth, are they not?

Dr. HAYS. Yes.

Mr. NAUGHTON. Didn't you have one product that you took off the market a few years back because it caused a number of deaths of children? I am speaking of thallium.

Dr. HAYS. That is correct.

Mr. NAUGHTON. Could you tell us about that situation?

Dr. HAYS. Well, there had been a number of reports of accidents and deaths associated with the use of thallium sulphate. It is and has always been looked upon as a highly toxic compound, but it was felt that it could be used safely and it was registered.

Experience showed, however, that the directions for use were not adequate to prevent the kinds of accidents that were occurring from home use.

Mr. BROWN. The nature of the use, please?

Dr. HAYS. It is used in homes as rodent control. The formula which was used, the paste, made it available for children to pick up the paste and to eat it, which resulted in some cases of injury and death. The Department, then, on the basis of these findings took action to cancel the use of this product.

Now, our action was based, I'm sure, on the premise that the cancellation of this product would prevent the continued proliferation of the product in interstate commerce and indeed this is precisely what happened.

Our records by our inspectors, who have been making a continuing review of any available thallium on the market, have found only an occasional lot or lots of thallium. The records indicate that the shipments had not been made after 1965 or after the cancellation. So, we believe that we have given the public protection by the cancellation. We did not make any attempt to withdraw the materials from the market on the premise that I just stated, that the cancellation would in itself prevent the continued proliferation and thus a phasing out, a dilution and finally disappearance.

Mr. FOUNTAIN. When was that cancellation, Doctor?

Dr. HAYS. That was in 1965.

Mr. NAUGHTON. How many deaths do you know or estimate resulted from thallium?

Dr. HAYS. I do not have that information, sir.

Mr. NAUGHTON. Would you say it is probably over 100?

Dr. HAYS. I just do not recall that particular bit of information.

Mr. NAUGHTON. Does anyone have any statistics on that?

Dr. ANDERSON. We have some data in the Division that was based on records of the report and control centers of the Public Health Service that we could get.

(The Department of Agriculture subsequently provided the following statement:)

STATISTICS ON THALLIUM PRODUCTS

The Pesticides Regulation Division, Agricultural Research Service, has no official statistics on the number of deaths due to thallium. We have acquired certain information regarding accidents involving thallium products. The primary source of this information is the Public Health Service, Division of Accident Prevention. Poison Control Center. Based on this information, the total number of accidents attributed to thallium products is approximately 400 during the period 1962 and 1963.

Mr. NAUGHTON. Most of these deaths would be children, of course?

Dr. ANDERSON. Yes.

Mr. BROWN. There is no deteriorating effect implicit in thallium as a product, is there? I want to be sure I understand what you mean by the phasing out of this as a danger. Are you suggesting that it is a dangerous product left on the shelves but eventually it will be used up as a dangerous product and therefore there will be no more dangerous products left on the shelf; or are you sugegsting that it is a product on the shelf that 6 months after it gets on the shelf it is no longer dangerous?

Dr. HAYS. No; I do not know the precise period of stability of this material. I suppose it is stable for a long period of time. But the quantities that apparently are on the market are relatively small and the cancellation was not based on any imminent or immediate wide scale deaths. They were very localized, as I recall, and indeed, with all of the materials that had been marketed up until that time it is quite apparent that it could be used safely and has been used safely by many people; but because of the inherent danger we felt the necessity to no longer permit the continued registration.

Mr. BROWN. Was this a danger that arose from improper use through ignorance or was the package label such that improper use would have had to be in complete contradiction to the advice on the package label?

Dr. HAYS. I presume that a good deal of that is improper use, even though the directions were adequate if followed, but obviously they were not being followed.

Mrs. DWYER. Would the gentleman yield?

Mr. BROWN. Yes.

Mrs. DWYER. Were any deaths of children reported after 1965?

Dr. HAYS. I know of no reports of any deaths of thallium in 1965 or 1966. I have seen no reports of any deaths.

Mr. FOUNTAIN. In other words, you feel that the precautions you are taking now are adequate to prevent this sort of thing from happening again?

Dr. HAYS. I hope so.

Mr. FOUNTAIN. In order to spotlight the importance of it, I might read some excerpts from the GAO report. The report says on page 11:

In June 1960, ARS took action to limit the thallium content of products in an attempt to reduce the possibility of fatal accidents associated with the use of such products. In spite of the limitation, deaths continued to occur as a result of accidental ingestion of the products. In addition, statistics of the Public Health Service indicated that there were about 400 reported cases of thallium poisoning of children during 1962 and 1963.

On August 1, 1965, ARS notified manufacturers, formulators, distributors, and registrants that the registrations of products containing thallium were being canceled. The cancellations involved 45 registrants and 58 thallium products.

According to ARS, the action was taken as a result of the continuing number of accidents associated with the general use of the products. The effective date of the cancellation of the registrations of the products containing thallium was 30 days after the registrants received the notice of August 1, 1965.

Our review showed that the action in August 1965 to cancel the registration of the products involved was not supplemented by action to obtain information on the quantities and locations of products that had previously entered marketing channels. We found that, subsequent to the cancellation of the registrations, thallium products continued to be available for public consumption and that efforts ARS made to protect the public, such as attempts to locate thallium products, were being made without knowing the locations or quantities of the products involved. We found also that a product containing thallium was still available to the public in January 1968 and that the extent and duration to which such products remained available to the public were unknown.

The report continues discussing this but I read it simply to indicate the difficulties you evidently have had in getting this product from the market and the dangers that were involved and the lack of adequate procedures at that time.

Mr. BROWN. Mr. Chairman, could we also ask for some indication of how that product was labeled? Do you have a sample of the label that was required on the products that contained thallium?

Dr. HAYS. We can supply that to you, sir.

Mr. BROWN. Could you give me any generalized idea of what that might say from your memory?

Dr. HAYS. Well, from the category alone, for highly toxic materials, there are certain things that must appear on the label of all products bearing this kind of danger.

In other words, if it is highly toxic, it must bear the term "highly toxic, poison, skull and crossbones," and the precautionary statements in its use, "avoid contact with the skin or avoid ingestion" or whatever it may be. I do not recall precisely what is on that label.

Mr. VANDER JAGT. Mr. Chairman, associated with that point, in your concern about the safety precautions and its possible effect on young children, does your authority include the right to specify the type of container, how easy it would be for a child to get at it, or is that outside your jurisdiction?

Dr. HAYS. We are very much concerned, Mr. Congressman, on this matter of containers. Indeed, we have taken very forceful action in regard to a number of products that had been registered over the years that we now regard as "attractive nuisances," things that we are fully convinced, in our present methods of living, have no place in the home; products of pesticides that are marketed in what we call little cartons in the shape of a garage or a church with a steeple, inside of which is a highly toxic poison.

These have been eliminated and are continuing to be eliminated from the market under provisions of the act. We consider this a very important part of our registration program. We look at any new registration and ask how the product is to be marketed, in what form, and in what package.

Mr. BROWN. I have here a package that is called Antrol, and apparently it is some kind of a product that has to be put on the floor. It is called an ant trap, and I notice that on the top of the package there is nothing but the name of the product. It says, "Ant trap kills ants." Then on the side, in letters that I would assume to be about the size of a normal newspaper type, it says "keep away from children and domestic animals."

It strikes me as a little difficult to do that if you place it on the floor. But then on the back in red ink is the name of the product in about 48-point type and in 12-point type is the word "Poison" and a little skull and crossbones, and then an antidote in very small type with capitalized letters, "Call physician immediately" and a warning about cumulative effect, about rubbing in the eyes and on the skin, but this warning is not nearly as prominent as the money-back guarantee if you are not satisfied with the product, and again with the name of the manufacturer and the guarantee that it will kill sweet ants and grease-eating ants.

Now, my question is whether or not there is any effort in any of these products to set standards concerning the labeling required on a dangerous product as it is used or on the package and I presume in this case the back of the device by which this is hung on the counter would have to qualify as a package.

I assume this product contains thallium and that it has been taken off the market altogether.

Dr. HAYS. That is right.

Mr. BROWN. But is there any size requirement on the label of the poisonous or dangerous product, or concerning a warning to keep away from children and domestic animals or the antidote or anything like that?

Dr. HAYS. Yes, Mr. Congressman. We do have requirements for certain type size for certain size containers. But more than that, we are very much interested in this matter of labeling, what we would call the adequacy of labeling. We are concerned about any accidents that occur with pesticides. It disturbs me when it might have been prevented by better labeling. So, we have asked the University of Illinois to make a very indepth study of the adequacy of labeling; to go back and review the history of labeling and then to see by a wide audience participation what labels mean to many people.

When this study has been completed, which ought to be within this next year, I hope that we may certainly correct a lot of the things that you have mentioned in the type size and where things should be placed on labels and what we can do to prevent any accidents from occurring.

Mr. BROWN. This is after you discover that the product is dangerous if used or ingested in some way other than to destroy the ants or the insects or the rodents or the fungi that it is aimed at. But how do you discover whether it is dangerous if used in an improper way?

Dr. HAYS. Well, of course. We rely on our continued surveillance of our pesticide program and reports of any incidents, whatever type of accident——

Mr. BROWN. In other words, if there is an accident, if somebody dies from eating this, then you check the product?

Dr. HAYS. Not if anybody dies, necessarily. For any accident that is associated with any pesticide we have a complete review by a group that I have assigned to this task. It is their responsibility to review every accident, regardless of what it is, to determine what the cause may have been and what we could have done to prevent it perhaps through labeling, whether it was an accidental ingestion, whether it was a suicide attempt, no matter what it was.

Hopefully, a thorough review will reveal things that we have not recognized in the past.

Mr. BROWN. If I may pursue this just for a couple of minutes—I don't want to strain the patience of the chairman. If you have reports of this product poisoning people, is that the first time you check on the danger that comes from the product, or do you, when the product is manufactured, require it to be checked out as to the nature of the danger?

Dr. HAYS. We check in terms of usage as to how it would be used.

Mr. BROWN. In terms of what the product will do if improperly used? The paste that you know the kids were putting their fingers into and eating, did you know how dangerous that product was when it was put on the market?

Dr. HAYS. Yes, through our registration process. Every applicant is required to submit data on both effectiveness and safety. The safety includes a variety of tests to determine what the degree of hazard might be, such as oral ingestion, skin absorption, inhalation, reproduction. Everything that we think would be necessary to prepare a label that, if complied with, would be adequate to protect the user.

Mr. BROWN. Do you check all that out in the laboratory or do you refer it to somebody?

Dr. HAYS. The applicant, the registrant, the manufacturer provides all of this data and we determine what is needed.

Mr. BROWN. And you take his word for it?

Dr. HAYS. We have his data that he has had supplied to him by toxicology laboratories to determine the toxicology.

Mr. BROWN. Do you check the product against that data to see that the data describing the product is accurate with reference to the samples of the product?

Dr. HAYS. The act does not require us to do pretesting of all registered products.

Mr. BROWN. Really the thing you have from which to work is what the manufacturer says about the nature of its product and what it contains and the danger from it?

Dr. HAYS. That is correct.

Mr. BROWN. When you start getting reports of a product that is resulting in deaths or injuries, whether accidental or in the normal use of the product, do you take any prompt action to take the product from the market or to warn the company or the people who might be distributing the product or the Agriculture Extension Service that might be promoting the use of the product.

Dr. HAYS. There are two things that we do, sir. If we have some real doubts and concerns, we would have our toxicology laboratory do tests on this particular product.

Mr. BROWN. But that is not done until there is a negative result, an injury or a death from a product?

Dr. HAYS. That is correct, sir; unless we would have some reason to doubt the submitted data.

Now, the second thing would be—and we frequently do this—where we have this concern, is to consult with the manufacturers and to see what can be done, perhaps in the way in which the material is used, the way in which it is dispensed, the kind of container, to again find a way in which it is not available to children.

Mr. BROWN. But nothing is done about those products which may currently be for sale at the corner drug store or feed store or wherever it might be to negate the use or the availability of those products in trade?

Dr. HAYS. Well, when we have received the data, both on effectiveness and safety, and we have concluded that on the basis of this——

Mr. BROWN. Now, wait a minute. What data are you taking about, the data provided by the manufacturers?

Dr. HAYS. When we have received the data that has been supplied by the manufacturer for the registration of the product, and it is not registered until we have evaluated this data——

Mr. BROWN. Evaluated in what way?

Dr. HAYS. In terms of safety.

Mr. BROWN. But not laboratory evaluation now?

Dr. HAYS. It would be an evaluation of their laboratory data.

Mr. BROWN. Which you are then looking at written down on a sheet of paper saying this is safe or not safe depending on the way it is used, but you get it from the manufacturer and you evaluate it in a think process rather than an examination process?

Dr. HAYS. That is right.

Dr. ANDERSON. Mr. Congressman, I might add that these products all have ingredient statements which list the chemicals that are involved. The toxicologists and the chemists have knowledge of the toxicity of the compound that was contained in the product. So, in that respect, they do not have to rely on the toxicity data supplied by the manufacturer because the toxicity of the products are generally known to all scientists.

Mr. BROWN. But you do rely on what the manufacturer says the product contains and do not check what he says it contains?

Dr. ANDERSON. Not prior to the——

Mr. BROWN. And do you check the packaging of the product to determine its labeling or its availability? Do you just take a registration mimeographed sheet on what the product is and so forth, or do you look at the package after it is prepared for market to see if it looks like strawberry jam or something?

Dr. ANDERSON. There are two things involved. First, it calls for label review. The label that they plan to use on the package is reviewed. As Dr. Hays mentioned, they are now giving attention to how it will be packaged in regard to any hazard that may be associated.

Mr. BROWN. But previously you took this off the typewritten letter report of the manufacturer?

Dr. ANDERSON. How long have we been reviewing labels?

Dr. HAYS. We have been reviewing labels since 1947, but the manufacturer is required to submit proposed labeling and a copy of his label.

Unfortunately, we cannot always tell the form of the package in which it is going to be marketed. This is why we have stated that we are deeply concerned about this matter of packaging, especially in attractive packaging that will result in injury. So, we feel the necessity now to require the manufacturer to submit detailed information as to how he is going to package his product and what it is going to look like.

Mr. FOUNTAIN. Mrs. Dwyer, I believe you had a question?

Mrs. DWYER. Yes. How many products are presently being marketed under ARS registration which the PHS or some other agency of the Government has expressed doubt concerning their safety or efficacy? By that, I mean when they could affect children or adults in some way.

Dr. HAYS. Well, we have some 45,000 products registered with the Pesticides Regulation Division and of that I don't think there is more than—I really don't know. I would say a half dozen in which the Public Health Service has expressed some concern.

Mrs. DWYER. Well, if you have a record of that, would you supply it to the committee?

Dr. HAYS. Yes, sir.

(The following information was subsequently supplied:)

CATEGORIES OF "OBJECTIONS" BY PUBLIC HEALTH SERVICE TO PESTICIDE LABELING—JANUARY 1, 1968, THROUGH MARCH 31, 1969

During this period, a total of 11,361 product labels had been referred to Public Health Service for review. They listed 252 as "Objections," all of which fall into the following eight basic categories of products. The problems involved have been discussed with representatives of the interdepartmental agencies in an effort to find ways of obtaining scientific data to either support or withdraw the objection.

1. Mercurials.
2. Concentrates stored around the home.
3. Seed treatments without a dye.
4. Bait materials.
5. Continuous vaporization in enclosed areas.
6. Potential carcinogens.
7. Continuous exposure.
8. Disinfectant fogging of hospital rooms.

Mrs. DWYER. Thank you, Mr. Chairman.

Mr. NAUGHTON. Dr. Hays, isn't the basic problem with thallium, as was indicated by Mr. Brown's questions, the fact that there is a contradiction in the labeling and that it cannot possibly be used effectively and safely as directed? In other words, you have an ant and a rat poison which is sold to kill ants and rats and is highly dangerous to children. If you keep it away from children it is not going to kill the ants and the rats, isn't that true?

Dr. HAYS. That is correct.

Mr. NAUGHTON. If you use it according to directions it presents a danger to children?

Dr. HAYS. I thought we had been discussing this matter, sir. With many registrants, this incongruity, such as the statement "Keep out of reach of children" when we know in fact that the only place you could put it would be in reach of children and we have objected and canceled the registrations of many products on this basis.

Mr. BROWN. Since when?

Dr. HAYS. In the last 6 months we have objected to some three or four different products that if marketed in the way in which they have them, would be extremely hazardous and they would have to be placed in an area where children could reach them.

Mr. NAUGHTON. Or course, you don't need a contract with the University of Illinois and a 2-year study period to know that if you put rat poison on the floor the children are going to get at it. Isn't the same contradiction in labeling inherent in lindane in that this product was registered for use on a continuous basis in restaurants? It is a con-

tinuous vaporizer. It puts vapor throughout the room 24 hours a day, 7 days a week, and the label says "Do not contaminate food." Could you tell me how you could possibly use this product in restaurants without contaminating food? There isn't any way in the world it could be done is there? Unless you put all the food in metal packages and never took it out?

Dr. HAYS. Well, I really believe, sir. that at the time this product was registered and at the levels which were present in the atmosphere, there was perhaps doubt in the minds of many that there would necessarily be contamination of food. At these extremely low levels and the rate at which it was being dispensed, however, data now does support what you have said.

Mr. NAUGHTON. You performed some tests in January of this year that indicate that the lindane vaporizers will result in residues on food and on utensils which exceed the tolerances for such residues that have been set by the Food and Drug Administration for other uses by several times, do they not?

Dr. HAYS. Yes.

Mr. NAUGHTON. When did ARS first become aware that PHS and the Food and Drug Administration had questioned the use of lindane in vaporizers as you had registered them?

Dr. HAYS. I guess this goes back to 1953.

Mr. NAUGHTON. Some 16 years ago. Why was it necessary for you to wait 16 years to perform your own tests and find for yourselves that the residues being left were considered dangerous or potentially harmful by FDA?

Dr. HAYS. Well, sir, I have been with the Division only since 1966. I cannot answer for that period of time from 1953 to 1966.

Mr. BROWN. May I inject a question or two at this point? Do you have facilities within the ARS laboratory facilities for conducting experiments of this nature? Is this part of that $3 million budget?

Dr. HAYS. Yes, we have facilities for doing tests at this time.

Mr. BROWN. So it is not necessary to contract that work. Did you have them in 1953?

Dr. HAYS. We did not have such facilities in 1953.

Mr. BROWN. When did you get them?

Dr. HAYS. I would have to refer that to Dr. Anderson.

Dr. ANDERSON. I cannot answer that, sir.

Mr. BROWN. Could you give me an approximation?

Dr. ANDERSON. We have steadily improved our analytical laboratories. I would say it was after 1960 before we had the capability to perform such a test.

Mr. BROWN. So from 1953 to 1960 or thereabouts you did not have the facilities to conduct the test, but since then you have had the facilities and the complaint by FDA and PHS has been submitted to you since that time?

Dr. ANDERSON. That is right. In connection with the three-way agreement, the agency objecting to the registration is required to submit data in support of their objection. This has been hard to come by.

Mr. BROWN. You mean this data was not submitted by either PHS or FDA?

Dr. ANDERSON. No, it was not.

Mr. BROWN. What form did the nature of their complaint take?

Dr. ANDERSON. It was on the basis of their opinion that its use should not be permitted in restaurants and in the home.

Mr. BROWN. But they did not give you any reason?

Dr. ANDERSON. I do not recall any data that would support such a hazard actually existed.

Mr. BROWN. Was this——

Dr. ANDERSON. It was a practice that they did not think should be permitted.

Mr. BROWN. They did not say why?

Dr. ANDERSON. Mainly, if I recall, they did not believe that the human should be submitted to the same concentration of a pesticide in the atmosphere as is required to destroy the pests.

Mr. BROWN. But you don't consider that was a warning against hazard?

Dr. ANDERSON. We considered that as a warning. We continued to search the literature and search for data that would show a definite cause and effect relationship. We could not find it.

Mr. BROWN. Was the complaint from Public Health Service or Food and Drug Administration only a one-shot affair? In other words, was this a letter or something written to you once that raised this question?

Dr. ANDERSON. No, sir. There was, you might say, a standing or a continuing objection.

Mr. BROWN. But that objection has never been reviewed in terms of studying your own laboratories?

Dr. ANDERSON. No, sir.

Mr. BROWN. Until recently?

Dr. ANDERSON. Yes.

Mr. BROWN. Who makes that decision to either ignore or to examine?

Dr. ANDERSON. Well, it starts out in the Division. It is concurred in at the different levels of responsibility in the Department. But, the decision to ignore it or to accept it is considered. We consider all the facts carefully and weigh them in connection with known evidence or data that would support the objection or the approval.

Mr. BROWN. Did you transmit this rejection of the expression of concern to either FDA or PHS?

Dr. ANDERSON. When those two agencies indicated that they objected to this use, we requested that they provide us with any scientific data in support of their opinion.

Mr. BROWN. So when one agency of the Federal Government didn't provide another agency of the Federal Government with that information, the second agency, that is, the Agricultural Research Service, decided that it wasn't necessary to pursue it further?

Dr. ANDERSON. As I said, we looked everywhere, journals, experts, in seeking data that would support either action.

Mr. BROWN. But you did not utilize the laboratory to make this examination?

Dr. ANDERSON. No.

Mr. BROWN. Was the reason you did not utilize the laboratory was that the laboratory was so busy checking new products? Was it a matter of the scheduling of the laboratory? Was there a problem in using the facilities that were available to you?

Dr. ANDERSON. No; it was not that. One thing that prompted us to move on to testing the product was the new information that became available in 1967 and 1968 which gave further evidence to us that injury could result from this use of lindane vaporizers. This prompted us to move ahead then to determine how much contamination was occurring.

Mr. BROWN. What new information was that?

Dr. ANDERSON. As I mentioned earlier, one was that the people suffering from malnutrition would be more susceptible to lindane toxicity than people that were normal.

Mr. BROWN. Where did the information come from?

Dr. ANDERSON. It was published in the Archives of Environmental Health of the American Medical Association.

Mr. BROWN. It was outside research that somebody who was interested in it, not from the standpoint of a responsibility under the law but as a medical problem, had pursued when the ARS which had the responsibility to pursue it under the law had not pursued it?

Dr. ANDERSON. That is correct. Under our understanding we do not conduct toxicity studies involving humans. We look to the other Federal agencies for that research.

Mr. BROWN. But the other Federal agency had apparently raised some question here and no action had been taken because they had not forwarded you the results of their tests.

Dr. ANDERSON. We continued to request data in support of their views.

Mr. BROWN. Well, if I may, Mr. Chairman, it just occurs to me that somebody in the Federal Government ought to be as much interested in protecting the health of people as a result of products which are registered by Government as private medical associations are in investigating the safety of products so registered. And if the Public Health Service says there is some question about the safety of a product on which the ARS has approved the registration, then it ought not to have to be an outside-the-Government agency 10 years later that determines that that product really is dangerous. It seems to me that either the Public Health Service or Food and Drug Administration or the Agricultural Research Service, which after all is the licensing agency, has the responsibility to pursue that question and eliminate it as a possibility under the law, under the medical facts and statistics.

I am terribly overwhelmed by this whole thing because I also sit in the Interstate and Foreign Commerce Committee where we are running through an exercise where apparently the medical evidence is highly contradictory with reference to the danger and the safety and efficacy of smoking cigarettes. And the Government is doing a lot of breast beating and table pounding about what ought to be done about cigarettes which they don't license and which is a product that has been in use for centuries. Yet, here we have a product which industry brings to the Federal Government for licensing, the Federal Government licenses it and we suddenly discover that two agencies of the Federal Government have raised grave questions about it. The third agency that has the responsibility for licensing it has never bothered to pursue those questions beyond saying send us your material and, when it didn't come, they said, "Ho hum, that is not our

problem." And we have got people suffering ill health, possibly death, as a result.

I think the inconsistency within the operation of the Federal Government is overwhelming. It never ceases to amaze me how the agencies who have a legal responsibility under law to do a job don't do it. And those that have no such responsibility are anxious to go ahead and try to do something that they don't have any legal responsibility for doing.

Now, I don't know what the answer is, except that maybe we ought to try something else to govern us besides Government.

Dr. ANDERSON. We believe that we have recently initiated actions between our agencies that will improve this situation. We had a meeting of the members of the three-way agreement and agreed that once a month the program people would meet to discuss these differences of opinion and identify means of resolving them. Whether it would be in-house research or whether it requires a contract or some other means of obtaining the information or requiring the manufacturer to produce the information.

Mr. BROWN. When did you meet and decide to do that?

Dr. ANDERSON. It was about a month ago, sir.

Mr. BROWN. After the GAO reports came out and so forth?

Dr. ANDERSON. Yes, sir.

Mr. BROWN. It occurs to me to wonder what you were doing with your $3 million a year before that and also what you were doing in this laboratory before that? Do you know how many products were run through that laboratory?

Dr. ANDERSON. We can supply that; yes, sir.

(The following information was subsequently supplied:)

PRODUCTS ANALYZED BY PESTICIDES REGULATION CHEMISTRY LABORATORIES AND TESTED BY PESTICIDES REGULATION BIOLOGICAL LABORATORIES DURING FISCAL YEARS 1960-67

	1960	1961	1962	1963	1964	1965	1966	1967
Chemistry laboratories	1,470	1,658	1,770	1,579	1,594	1,627	2,393	3,979
Animal biology laboratory						155	133	139
Entomology laboratories		101	50	88	103	41	91	100
Microbiology laboratory	317	394	386	517	534	431	618	863
Pharmacology laboratory	39	121	93	101	316	563	638	338
Plant biology laboratories	20	17	101	77	117	138	215	362
Total, biological laboratories	376	633	630	783	1,070	1,328	1,695	1,802

Note: Based on past records, approximately 621 out of 1,000 products tested involve different manufacturers.

Mr. BROWN. And how the products that you did test in that laboratory were selected for tests?

Dr. ANDERSON. Yes, sir. There has never been any information or evidence to show that harm or injury has resulted from this registered use. The registered use was determined——

Mr. BROWN. Except from those letters from FDA and PHS saying while it killed insects it might not also be good for humans.

Dr. ANDERSON. Yes, sir.

Mr. BROWN. Until the AMA did the study or whatever it was.

Dr. ANDERSON. It was also reviewed with environmental health people who were of the opinion that the concentration the people were exposed to did not constitute a health hazard.

Mr. BROWN. But no effort was made to resolve the contradictory evidence between all the other agencies and you who had registered the product?

Mr. FOUNTAIN. I hate to interrupt, Mr. Brown.

Mr. BROWN. I am sorry.

Mr. FOUNTAIN. I might add the longer you are here, the more you will be overwhelmed, not less, at the way the Government operates.

Mr. BROWN. We ought to have a committee to investigate this sort of thing.

Mr. FOUNTAIN. There are a number of questions we would all like to ask you but the limitations of time are such that we are simply trying to show what the situation has been and what you are doing. I might add for the members of the committee that the record will show much documentation and information concerning what has transpired and, of course, these two reports of the General Accounting Office are really frightening with respect to what has transpired and what may have happened that we don't know anything about.

So, I am going to proceed with the questioning in order to get the basic features on the record, and then we will get into some other questions within the limitations of time.

Mr. NAUGHTON. There has been some mention of an interagency agreement with respect to settling differences between agencies as to whether or not a product should be registered for a particular use. What period of time does the interagency agreement provide should be allowed for the resolution of these differences?

Dr. ANDERSON. I believe that the agreement provides that any opposition to a registration would be supported by scientific data within 14 days, about 2 weeks.

Mr. NAUGHTON. Let me read from the interagency agreement and I am quoting verbatim.

> In the event agreement is not reached among the Department's representatives within 2 weeks of the initial objection, the matter will then be referred directly to the Secretary of the Department responsible for final action with such information, views, and recommendations as the three Department representatives deem appropriate.

Now, Dr. Hays, when you were chairman of the task force on pesticides regulation division in 1965. November 1965, do you recall making a comment in the report on whether or not this provision for the settlement of differences was being followed?

Dr. HAYS. I really don't recall, sir. I have not reviewed that report for some time.

Mr. NAUGHTON. Let me read from page 32 of that report in which the comment is made "The provisions in the agreement for settling differences between agencies simply have not been followed." Item B of the agreement states that if there is reason to question any of the items on the list this will be communicated to the originating department within 1 week stating the specific reason for need for further review. And it goes on to make a number of objections to the fact that these differences were not being resolved.

Yet the differences on lindane not only were not resolved for a period of perhaps 11 or 12 years prior to the adoption of the interagency report but for a period of 4 years or more after the adoption of the report.

Now, when you became head of the Pesticides Regulation Division after criticizing in your report the failure to reach agreement, did you take any strong action to see that agreement was reached and is lindane an exception to that rule or did you take no action and continue to follow the course you had criticized in your report?

Dr. HAYS. We had taken steps to discuss this matter with the Public Health Service. My effort was directed at trying to get such data as would make it possible to come to some judgment as to the hazards associated with this use.

Since this was a provision in the agreement and certainly a very important one, I felt that we had no recourse than to do what we have done in the intervening 2 years.

Mr. NAUGHTON. Excuse me, Doctor. Are you saying in retrospect you couldn't have done any better in the last 2 years than the record shows that you did?

Dr. HAYS. I suppose other steps might have been taken. But, as you read in the interagency agreement, there is a provision for the settling of these differences. But, when you have no information to transmit to any other group for review, and in this instance we had nothing except statements that were made that there was some danger associated with this use, I felt as a scientist that we needed supporting data for this objection. If it is that important and if it is that obvious to the objecting parties, then the data must surely be available somewhere for submissions to USDA.

Mr. ROSENTHAL. Did you go out seeking the data?

Dr. HAYS. We made a review of all the information that we could find in the literature. But, if Public Health Service had other data to support this objection, it seemed to me only right that this data should be made available to us.

Mr. ROSENTHAL. Did you ask them for it?

Dr. HAYS. Yes.

Mr. ROSENTHAL. What was their response?

Dr. HAYS. They had no data, except what we already had. It was simply a matter of professional judgment. Now, if all of pesticides are going to be placed in dispute on the basis of professional judgment, then, Mr. Chairman, we are going to be in some trouble.

Mr. FOUNTAIN. How many products?

Dr. HAYS. We have 45,000 products. Therefore, I think it was very wise in the preparation of that agreement that this provision was made that would give us some basis on which to act. Now, there is a question among many people about this matter of lindane. If it had been something very overt, something you and I could recognize beyond any question of doubt, the course of action is clear. But I assure you, sir, that there is a considerable question of doubt in the minds of many people in science as to the effects of lindane. This is perhaps one of the insidious types of effects that are not always well recognized, and I think it is here that we need this kind of help from the participating agency to give us that kind of data to make good sound judgments.

Mr. NAUGHTON. Is it your position, Doctor, that when in doubt, as to safety, leave it on the market, until somebody proves it or you get fatality reports?

Dr. HAYS. No. Mr. Chairman, we have used this term "safety," "doubts of safety." I would like just to point out that if we set out to resolve all of the questions and doubts as to safety, then I think we have an almost insurmountable problem, because I do not know, personally, as a toxicologist and pharmacologist, just what I would do to prove that a product is safe.

What I can do sir, is to determine the harmful effects by the studies that are conducted on laboratory animals and then extrapolate this data to man. I can point out the hazards associated with that product. But it would take an infinite number of years, a lifetime perhaps, and human studies, to be sure that a compound is safe.

I do not know, as a scientist, how you determine that degree of safety.

Mr. NAUGHTON. Is the Food and Drug Administration not the Agency within the Federal Government that has primary responsibility for determining what tolerances should be allowed in terms of residues left on food?

Dr. HAYS. Yes.

Mr. NAUGHTON. You never submitted it to Food and Drug?

Dr. HAYS. No.

Mr. NAUGHTON. Your tests established that if you took the tolerances established by the Food and Drug Administration for these other uses of lindane that the residues left by lindane were illegal?

Dr. HAYS. This is not a raw agricultural product requiring a tolerance. This is an adulteration of food in restaurant uses. This we tried to establish. In 1953, there were studies, Mr. Chairman, on the exposure of food.

Mr. NAUGHTON. Can we stay back in 1969 when you made the tests?

Mr. BROWN. Let me pursue the point.

Dr. HAYS. In 1953, there were studies on this type of approach.

Mr. BROWN. On lindane?

Dr. HAYS. On lindane, that is correct. But, unfortunately, that data indicated that in this particular experiment, the amount used was about four times the concentration that would be expected to appear in the atmosphere from the directions for use. So, this data really had no significance.

In addition, the foods were exposed for 30 days under unrefrigerated conditions, and so again this made the interpretation of such data very difficult.

Therefore, we started our studies in February of 1969 and tried to simulate the conditions that one would find in a restaurant, and under proper refrigeration, exposing the food only 5 hours and then refrigerating it and then again the next day for 5 hours, and also the instruments, the spoons and forks and tableware and so on.

After 5 days of exposure, we did in fact find under precise conditions of use that there was a residue of lindane on these instruments as well as in the food.

Now, I think this is reasonably a part of our conclusions that under normal directions of use you cannot possibly prevent this sort of contamination.

Mr. BROWN. Who made that experiment in 1953?

Dr. HAYS. I don't recall the authors of that paper.

Mr. BROWN. Was it within the agency or outside?

Dr. HAYS. I think it was in—I believe it was under the Food and Drug at that time.

Mr. NAUGHTON. After some 16 years when you finally decided to make the test it took you 5 days to make it?

Dr. HAYS. That was only a part of the study. The other, of course, was a reevaluation of the clinical aspects. This is where it took a considerable amount of time and good judgment on the part of our clinicians to come to a view that we think is a very reasonable one. It does not establish in fact the cause and effect relationship.

Mr. NAUGHTON. The basic problem in lindane as in thallium is that it was registered for use with directions on the label not to contaminate in one instance and to keep away from children. But you couldn't use it and keep it away from children, and in the other instance you were registering lindane for use on a continuing basis in restaurants and saying on the label, "do not contaminate foodstuffs." And you couldn't use it that way and not contaminate foodstuffs. Now, do you have any other vaporizers—whether they are chemical vaporizers or whether they provide a vapor through other means—that are presently being registered for use in homes where they could be used in kitchens?

Dr. HAYS. Vaporizing devices? We have no vaporizers.

Mr. NAUGHTON. It is not a vaporizing device. It is a product that vaporizes through some sort of chemical action.

Are you satisfied that the vapona is safe and will not contaminate foodstuffs in accordance with the tolerances established by Food and Drug?

Dr. HAYS. We have no data on any simulated conditions to see whether or not the food would be significantly contaminated.

Mr. NAUGHTON. You received no objection on vapona from the Public Health Service?

Dr. HAYS. Not to my knowledge.

Mr. NAUGHTON. Have they ever warned you or suggested that the label should bear a warning that this should not be used where infants or elderly people may be?

Dr. HAYS. Yes.

Mr. NAUGHTON. Have you taken action to require that this be done?

Dr. HAYS. Yes.

Mr. NAUGHTON. How effective do you think your action has been and when did you take it?

Dr. HAYS. I think this registration was brought about about 3 months ago.

This was a matter of great dispute on this question of requiring a precautionary statement on both pyrethrins and vapona where it says do not use this in areas where children or infants or aged or debilitated patients may be confined. We think this is a reasonable precaution.

Mr. NAUGHTON. Have you taken any action to require relabeling of products that are now on the market?

Dr. HAYS. No. We don't see any particular need for recalling these.

Mr. NAUGHTON. Have you taken any action to publicize the fact that vapona might be dangerous to infants and elderly people.

Dr. HAYS. We have had no publication of this.

Mr. NAUGHTON. I have a product here manufactured by the Shell Chemical Co. which we obtained in the Washington area in the last

few days, and it bears no warning that it should not be used in the presence of infants or elderly people.

Aren't you a little bit concerned that somebody might hang this above a crib for a couple of months—the Public Health Service apparently thinks it might be dangerous.

Dr. HAYS. I think both the Public Health Service and the Pesticides Regulation Division agree that this is an advisable thing to do. I have had no such suggestion from the Public Health Service that we recall all material from the market to relabel with this statement.

Mr. ROSENTHAL. Is it possible that you relied on the Good Housekeeping seal of approval that is on there, that maybe you can rely on that. They probably tested it. It is probably OK. You don't rely on that?

Dr. HAYS. No, sir.

Mr. FOUNTAIN. Dr. Anderson, in your statement you indicate that to the extent that recall actions are effective, there will be no necessity to resort to seizure action, and you also indicate that you believe your recall program has been effective during the first 10 months of fiscal year 1969.

Did you make any requests for recall during this period which were refused?

Dr. ANDERSON. Mr. Miller will speak to this.

Mr. FOUNTAIN. Mr. Miller, can you respond to that question?

Mr. MILLER. Yes, sir. We made one request recently for the recall of a product which was refused. It was refused initially.

Mr. FOUNTAIN. Did you have to seize it, or did they finally recall it?

Mr. MILLER. In accordance with our presently established procedures, we immediately obtained product location data and within a matter of days, actually, from the refusal to recall the product, we had multiple-seizure requests in the General Counsel's office.

As a matter of fact, we have eight separate seizure requests in the General Counsel's office. At that time the company changed its mind and decided to recall the product, so that the multiple-seizure requests were not processed by the General Counsel's Office. But we did have the requests there.

Mr. FOUNTAIN. But they were given the opportunity for voluntary recall action?

Mr. MILLER. Yes, sir.

Mr. FOUNTAIN. In your statement, you indicate that an indictment was handed down by a grand jury in Chicago this year charging violation of the act. When was this case referred to the Department of Justice for prosecution?

Mr. MILLER. Mr. Chairman, I am not sure of the dates on this. This particular criminal file was being worked on in our Division starting almost a year ago. It was sent by our Division to the Office of the General Counsel in the fall of last year. I cannot give you the exact date, but I believe it was referred by the Office of the General Counsel to the Department of Justice sometime around the first of the year.

Mr. FOUNTAIN. First of this year?

Mr. MILLER. Yes, sir.

Mr. FOUNTAIN. How long had you known about this case?

Mr. MILLER. About this particular company?

Mr. FOUNTAIN. Yes. The alleged violation, how long had you known about the violation before you referred it to Justice?

Mr. MILLER. The file was brought up to date. As a matter of fact, the principal violations which were used in the indictment were violations of last summer and early fall. But this company, I might add, has a history of violations under the act, which we were aware of.

Mr. FOUNTAIN. Prior to that time, when was the last previous case sent to Justice for prosecution?

Mr. MILLER. Well, the GAO report refers to a 13-year period, and we don't quarrel with that finding.

Mr. FOUNTAIN. When did information concerning the alleged violations relating to this Chicago situation reach the desk of those ARS officials who are responsible for preparing the case for prosecution? Do you have those dates?

Mr. MILLER. Well, I will answer your question this way, Mr. Chairman. A prosecution and import section was created in the Division in December of 1967. Very shortly after that section became operational, files relating to this company were being worked on by this section.

As a matter of fact, this was the first company whose actions were reviewed in this section. So, it would have been in the early part of 1968.

Mr. FOUNTAIN. Prior to 1967 you had no prosecution section?

Mr. MILLER. There was no separate prosecution section; no, sir.

Mr. FOUNTAIN. Your statement indicates that two official files have been forwarded to the Office of General Counsel of the Department of Agriculture with the recommendations for prosecution. When were those files referred? And when did the alleged violations take place?

Mr. MILLER. Both of those files were referred to the Office of General Counsel, I would say, approximately a couple of months ago.

In one of the cases there were three alleged violations, one of which occurred approximately a couple of years ago, and two are of a more recent nature, fairly recent as these files go. With respect to the other company, I would say it is about a year old.

Mr. FOUNTAIN. Dr. Anderson, on May 22, 1968, I believe you wrote a letter to the General Accounting Office commenting on a draft of the first GAO report which had been sent to you for review.

In your letter you indicated that the prosecution and import section had been created within the Pesticide Regulation Division of ARS in December of 1967 and that this section had become sufficiently staffed in January 1968 so that work could be commenced on setting up procedures for the handling of prosecutions.

You further indicated that you were currently reviewing all cases in the recent past to determine whether or not criminal prosecutions should be recommended. In view of these statements, am I correct in assuming that there were no procedures for the handling of prosecutions prior to January 1968?

Dr. ANDERSON. Consideration was given by the Division for action requiring prosecution, but for a specific guideline as to what would be referred for prosecution, I would say no.

Mr. FOUNTAIN. Will you submit to the subcommittee for its records any procedures you might have had or anything on the subject, even though you may not have had your prosecution procedures.

(The following statement was subsequently supplied:)

PROSECUTIONS PROCEDURES

There were no formal, established guidelines prior to January 1968 other than the provisions set forth in the statutes for requesting prosecution.

Mr. FOUNTAIN. What other duties does the prosecution and the import section have, if any, besides handling prosecutions?

Dr. HAYS. Only preparing the briefs for prosecution and handling of our imports, just those two areas.

Mr. FOUNTAIN. How many staff members did the prosecution and import section have as of January 1968, and how many does it have now?

Dr. HAYS. We had one man assigned with one clerical help, one person.

Mr. FOUNTAIN. Just one man.

Dr. HAYS. One man. That is the present staffing because of personnel ceilings. What additions we have made, we have currently assigned to our case review and development sections.

Our next staffing will be in the prosecution and imports.

Mr. FOUNTAIN. In your statement this morning you indicate that cases involving approximately 20 additional companies are being prepared for prosecution. How many people would you say are working on these cases on a full-time basis?

Dr. HAYS. Sir, we have just this one man at the present time. He is now preparing and will have ready two or three additional briefs. And we are extremely hopeful that we can increase the staffing in this particular area.

Mr. FOUNTAIN. Do you have people in other sections that could be transferred to the prosecution section? Are you equipped for this sort of thing?

Dr. HAYS. I think this could be done, of course, always at the expense of the work that is being done in those other areas.

Mr. FOUNTAIN. Do you have an opinion as to how long it will take the staff you do have to finish the preparation of these cases if they don't start any new cases in the meantime?

Dr. HAYS. Do you have any figure, Mr. Miller?

Mr. MILLER. I wouldn't want to guess, Mr. Chairman, as to how long it would take to completely review all the work involved with these 20 cases.

Mr. NAUGHTON. Isn't it likely he would have more than 20 additional cases in backlog by the time he finished those cases, if you have just one man?

Dr. HAYS. Yes, that is quite possible.

Mr. NAUGHTON. And the one man who is working on the prosecutions also has responsibility for the entire import program, supervising with the Customs Department all imports of pesticides?

Dr. HAYS. That is correct.

Mr. BROWN. May I pursue some questions on the legal nature of this, if you are finished in that area?

Mr. FOUNTAIN. Go ahead.

Mr. BROWN. First, it occurs to me to suggest that you might get some of these people out of the laboratory to help the legal prosecutions. Let me ask, as an individual citizen if I am injured by a product that has been approved by the Federal Government, does it affect my

case one way or the other that the Federal Government has approved that product for general use?

Mr. MILLER. You are getting into a field of civil liability that I don't believe that I am competent to give you a definitive answer on, sir.

I will say this, that any time there is a civil suit for damages involving a registered product, one side or the other, depending on which side it might be most favorable to, always brings it up.

Mr. BROWN. This is precisely my point, of course. I think you are aware that one reason we got into product safety at the Federal level was because the courts began to decide against the manufacturer of the product and the longtime theory of caveat emptor, let the buyer beware, began to go down the drain.

And the individual was being protected against a faulty product and the manufacturer was being required increasingly by the courts to guarantee the safety and efficacy of their products.

Then all of a sudden the Federal Government saw this as a good place to employ a lot of people to do the job for the manufacturer by registering the product, and we now have the Federal Government in this area in large measure. And what we are hearing this morning is how well they are doing that job.

My question is, in a civil action by an individual against a manufacturer in the case of a harmful product, is his case helped or hurt by that product having this seal of approval of the Federal Government?

Mr. MILLER. I wouldn't want to attempt to give you an answer to that, sir, because there are numerous cases in the various State courts which—well, the findings vary.

As a matter of fact, I believe there is a recent one in the past 1 or 2 years, a Texas case, which as I recall held that Federal registration does not necessarily mean that the manufacturer was not negligent.

Mr. BROWN. They must read these hearings. That is all I wanted to ask.

Mr. NAUGHTON. The act requires, does it not, that notices of judgment should be published when you seize a product?

Dr. ANDERSON. Right.

Mr. NAUGHTON. Is it true that for a period of more than 4 years no notices were published.

Dr. ANDERSON. That is correct.

Mr. NAUGHTON. What is the reason for that?

Dr. ANDERSON. One of the reasons was that it occurred at a time when we had a terrific increase in registration workload. The amended law required that the registration number be placed on all labels within a specified period of time. Over about an 18-month period, we were required to review about 45,000 labels. The single man that had formerly been concerned with preparing these notices of judgment retired, so that the activity was not picked up until more recently.

Mr. NAUGHTON. You are still not caught up to date?

Dr. ANDERSON. I believe——

Mr. NAUGHTON. I have seen two compilations come out, but you have a backlog of several hundred.

Dr. ANDERSON. We expect to be up to date by July 1, with a program of published notice of judgments every 6 months.

Mr. NAUGHTON. Now, Dr. Hays, the report of the task force that you headed in November 1965 indicates that the membership was made up of what appears to me to be either Federal, State, or local government officials, with one exception; namely, Roy Hansberry, Agricultural Research Division, Shell Development Co., Modesto, Calif. Would I be correct to assume that he was employed by private industry? Was any other member of the task force, to your knowledge, not a Government official?

Dr. HAYS. Except myself.

Mr. NAUGHTON. Well, you were the director of the National Advisory Center on Toxicology in the National Academy of Sciences and the National Research Council. It is a quasi-governmental agency; is it not?

Dr. HAYS. Yes.

Mr. NAUGHTON. It is federally supported and performs Federal functions?

Dr. HAYS. It is not a recognized Government agency.

Mr. NAUGHTON. Do you know how Dr. Hansberry, or Mr. Hansberry came to be appointed to the task force?

Dr. HAYS. No.

Mr. NAUGHTON. You did not select the membership?

Dr. HAYS. I did not make the appointments.

Mr. NAUGHTON. Is the Shell Development Co. related to the Shell Research Co. which puts out vapona?

Dr. HAYS. I presume so.

Mr. NAUGHTON. Did anybody raise any question as to possible problems in having an employee of a company manufacturing pesticides, one of which at least is in some question, on a task force of this kind?

Dr. HAYS. I don't know of any questions being raised.

Mr. NAUGHTON. Did the task force have access to data provided by manufacturers as to the makeup of their products, which is normally considered confidential?

Dr. HAYS. Our review really did not get into such things such as data which would have required very careful screening of every member of the task force.

Mr. NAUGHTON. Mr. Chairman, since we have mentioned this report several times, it might be advisable to place it in the record.

Mr. FOUNTAIN. If there is no objection, the entire report will become a part of the record.

(The report appears in the appendix on p. 248.)

Dr. ANDERSON. Mr. Chairman, if it would be proper, we would be glad to submit in addition to this, the actions taken by the Department to carry out the recommendations found by that task force.

Mr. FOUNTAIN. I think that would be good.

(NOTE.—A statement concerning action taken to implement recommendations of the task force was subsequently supplied. It is not being included in the record at this point because substantially identical material was included in a statement presented by Dr. George W. Irving, Jr., Administrator of the Agricultural Research Service, at a later hearing on June 24 and appears in the hearing record on p. 48.)

Mr. NAUGHTON. I might also ask that you comment with respect to questions that have been raised about how Dr. Hansberry came to be appointed and the questions involved and what your policy will be in

the event you have a further task force of this type with respect to industry representatives or employees.

(The following statement was subsequently supplied by the Agricultural Research Service:)

In selecting the membership on the task force, the Department felt that industry should be represented since we had been criticized for prolonged and unnecessary delays in processing applications.

Dr. Hansberry was chosen because of his long years of experience in research and his participation as a member of the "No Residue"—"Zero Tolerance" Committee, National Academy of Sciences, National Research Council. Dr. Anderson, then Deputy Administrator for regulatory and control, discussed Dr. Hansberry's appointment with Dr. Hays by phone and Dr. Hays concurred in his appointment.

The only minutes available are those for the first meeting. The chairman, Dr. Hays, decided there was no need for a secretary or minutes. No member of the task force had access to any confidential information and the members were verbally instructed to limit their review to areas assigned to them. Dr. Hansberry made a study of laboratory facilities and equipment, personnel, and methods of testing. A conflict of interest form (SF-68 or AD-392) was filed by Dr. Hansberry. We have contacted the Records Center in St. Louis and the form cannot be located. Since retention time is 2 years, we assume it has been destroyed.

The policy of the Department in setting up a task force is to select the best qualified personnel available but without conflict of interest. Whether Dr. Hansberry would be selected in a new task force would depend entirely upon the type of study to be conducted.

Mr. FOUNTAIN. You don't need so much study now, you need action. Mr. Nixon has talked about crime, and he made a right good statement. It is the followthrough that counts.

I am a great advocate of research, but I can't help but feel that as we take an inventory of what is happening in a lot of research agencies that maybe there has been an overemphasis on research as compared with the needs in order areas. And maybe there ought to be more emphasis in some of the other areas in getting action, because you can engage in all the research you want to and find all the answers, but if you don't use those answers and—of course, this record, to me, is incredible. It would make the Food and Drug Administration look good.

Mr. BROWN. Let me point out, Mr. Chairman, that the Food and Drug Administration and the Public Health Service did not follow up beyond the initial concern. By comparison, they do look good, but taken in the overall, the caveat emptor is the taxpayer who gets stuck.

Mr. NAUGHTON. Dr. Hays, there isn't any question about the dangers inherent in thallium when children eat it because there have been deaths from it?

Dr. HAYS. Yes, sir.

Mr. NAUGHTON. And the record would show that you became aware of those dangers certainly at least as early as 1960. You took steps to cancel the registration in 1965, and as the GAO report shows, about 20 percent of the establishments they sampled in the Washington area in 1968 were still carrying thallium products, some of which don't have appropriate warnings on them.

Now, of course, you do make checks when the products are brought in for registration and try to ascertain on a study basis what the dangers are and so forth, but some of them probably you can't foresee. Others that you should be able to foresee weren't foreseen in the past.

What arrangements do you have to be certain that the resources of

the Federal Government, the resources of State and local governments are utilized to the fullest extent possible so that the Pesticides Registration Division will receive prompt and as comprehensive as possible reports on deaths or serious injuries, or harmful effects resulting from use of registered products or from products which should be registered that are not?

Dr. HAYS. Well, sir, we do have a very extensive cooperative program with the Association of American Pesticide Control officials. It has been of real concern to me to develop a program whereby we can sit down with these officials to discuss Federal and State problems. We have held, in these past 2 years, eight regional meetings at which we have had present practically all of the State officials.

Now, in this kind of a program, we have attempted to work out a method whereby the State officials will report to us any incidents or accidents associated with pesticides. But we could cooperatively——

Mr. NAUGHTON. It is a very comprehensive question, and since we have a time problem, I wonder if it might not be more appropriate if you submit for the record a full account of the arrangements that you have and how well you think they are working and any thoughts that the Department of Agriculture may have as to how they could be improved.

(The information supplied follows:)

PROCEDURE FOR ACCIDENT INVESTIGATION

The pesticide accident reporting network was established in 1966 and consisted of personnel from the Plant Pest Control Division, Animal Health Division and the Pesticides Regulation Division of Agricultural Research Service, and the Pesticide Coordinators of the Federal Extension Service. The Plant Pest Control Division was designated as the coordinating office for the Department. It is presently proposed that the Pesticides Regulation Division will be designated as the coordinating office for the Department and given responsibility for the investigation of pesticide accidents. It is also proposed that the Plant Pest Control and Animal Health Divisions will render assistance in the actual investigations if needed. State pesticide control officials have been encouraged to relay information regarding accidents to the various Federal field offices.

Th reporting system appears to be working very well with initial reports being received from all participants, Federal, State, and local.

Now, getting again to the question of labeling, I am sure most of us sitting here have heard the cold power jingle about germproofing.

Dr. HAYS. Yes, sir.

Mr. NAUGHTON. Does cold power kill germs?

Dr. HAYS. Let me state it in this way: I am not really familiar with the advertising that has been reported to occur on television in terms of cold power. I really haven't seen it myself or heard it. It has been brought to my attention, the extensive advertising of cold power.

The cold power with a material or germicide added to cold water would at most be bacteriostatic and therefore would only inhibit the growth of bacteria.

So, in response to your question, it would not then, I think, kill germs.

Mr. NAUGHTON. Then in the normal understanding of most people in this room, it would not germproof, would that be correct?

Dr. HAYS. Well, again, when this matter of germproofing came into being many years ago, I believe it was the general concept in the

Webster's Dictionary, that at most the term "germproof" would mean providing resistance to growth.

Now, when these products were first registered, I am convinced that we were thinking in terms of inhibiting growth of bacteria in relationship to odor. In that context, we thought nothing wrong with the use of the term germproofing.

But times have changed. Advertising has changed and promotions have changed, so that this word "germproofing" has taken on a whole different context of implying that it prevents cross-infection by pathogenic organisms which we know is not true. Therefore, we issued a notice in the Federal Register defining these terms of germproofing, germproof, and germproofed, which I believe, sir, will bring about a resolution to this problem which concerns you and a good many people.

Mr. NAUGHTON. You would agree that when the ordinary individual hears the term "germproofing," he is not thinking of a substance that germs don't like; they are thinking of a substance that is proof against germs.

Dr. HAYS. I agree, sir.

Mr. NAUGHTON. Along that same line, the Department of Agriculture under the act has responsibility for registering hospital disinfectants. Does that fit in with your other responsibilities? Do you have any people who normally work in the area of hospitals and in the medical areas as opposed to the agricultural field?

Dr. HAYS. We do not have any people working in the area of hospitals. But, we do try to maintain a very careful surveillance of products that are used in hospitals by sampling on the markets. As was pointed out in the presentation, we have been very much concerned about this matter of disinfectants. Because, unlike the insecticides, we can see the insects killed. In the case of herbicides, we can see the weeds die, but you cannot see the germs or the bacteria die.

I am deeply concerned over it, because I have visited several hospitals to review their problems of sanitation, and especially in this age of medicare and the number of elderly people that are going to be confined to hospitals, and the great increase in susceptibility of the infants and the age to cross-infections, I am very much concerned. So, we have taken drastic steps to upgrade our requirements for registering products that fall into these categories.

This is not an easy thing because bacteriology is a science that is so very different from those other areas that we have under the act.

Mr. NAUGHTON. Wouldn't the Food and Drug Administration and the Public Health Service be better able to perform these particular responsibilities since their functions—at least as far as drugs are concerned—are directed toward the medical area?

Dr. HAYS. I think we have competent scientists in our area of bacteriology that are doing a very effective job. I do not know that any group would have done any better job.

Mr. NAUGHTON. How does your manpower in this area compare with that of the Public Health Service in terms of scientific competency? I am not speaking of the competency of the individual, but the quantity. Do you have any M.D.'s working in this area?

Dr. HAYS. We have no M.D.'s working in this area, and I could not give you——

Mr. NAUGHTON. I doubt they have very many veterinarians over there. Perhaps Food and Drug does, but PHS would not.

Mr. FOUNTAIN. One of the unfortunate things about this sort of thing is that it probably leaves an erroneous impression about pesticides. I think we all realize that in the kind of world in which we live, for the production of food and other products, and in countless other ways, we have got to have pesticides. They have been a tremendous service. And such a long period of time has elapsed without any careful check, when you disclose it all at one time, it may leave an unfavorable impression. That is the thing that disturbs me about this kind of situation. It seems to me that if a product is determined to be useful and necessary, it should be put on the market; that one of the most important things that can be done, as is true in the case of drugs, is to be sure that it is adequately labeled so that the man who buys it can read whether it is dangerous, and if he knows it is dangerous, is not to be put in a place where children or any humans may accidentally get hold of it, like on the counter in the kitchen or other places where people are likely to get some in their system.

Every precaution ought to be taken, it seems to me, to advise the person who buys it that that is what he is getting. I think, regrettably, the consuming public is of the impression—and it is not true—that everything that goes on the market has been determined to be safe and that they are justified in purchasing it. And that is also true with respect to drugs.

I think people when they use drugs, they have the feeling that Food and Drug has made an adequate check and that this drug is safe to be taken for the purpose for which the doctor gives it. But in many instances the doctor does not give all the information, or maybe the drug is not adequately labeled, and that is why we have these constant checks and changes in labeling procedures.

It seems to me this is one of the most important things, labeling. The question I wanted to ask following that statement is: Do you have adequate procedures, or is the law strong enough to enable you to take whatever action may be necessary to see that an item which is placed on sale to the general public is properly labeled as to such dangers as may occur from its use?

Dr. HAYS. I think we do, sir.

Mr. BROWN. Mr. Chairman, if I may just follow up on your remarks, I think that the public has the right to assume, if laws have been written requiring an agency of the Federal Government to approve and to register a product, based on its efficacy and safety, then the product is efficacious and safe, and I think that is what these hearings are all about.

It is an additional responsibility taken on by the Federal Government as a result of the Federal Insecticide, Fungicide, and Rodenticide Act. And the reason I asked the question I did with reference to the effect of a registered product being damaging to the individual is that the Government is not a party in the suit. They take a responsibility for saying that a product is safe, and then when it turns out that it is not safe, because the Federal Government has not done its job, the poor individual member of society has really been had, not only by the manufacturer, but by Uncle Sam, in the process.

I just wonder if there is not a legal principle that ought to be explored here that would assure the responsibility of the Federal Government when it fails in its responsibility under the law to have done a job that it is charged by law with doing. It would certainly be a change in legal principles with reference to the possibility of Uncle Sam being sued.

And what about the people who have the responsibility of doing the job being so thoroughly protected by civil service and the maintenance of their position regardless of whether they do their job with good judgment or not. It seems to me there is some pretty fundamental questions that have to be asked.

I presume—if I may—that all these people who are in the Agriculture Research Service, some 267 of them, including 100 in the laboratory services area, are civil service-protected; is that not correct?

Dr. HAYS. Yes.

Mr. FOUNTAIN. I might say at this point that the record will include along with the statement a copy of the Federal Insecticide, Fungicide, and Rodenticide Act, and a statement describing the interdepartmental information relating to insecticides, a statement describing functions of the Pesticides Regulation Division, and a chart showing the organization of the Pesticide Regulation Division.

Mr. NAUGHTON. That chart is not very legible, and I do not think we should put it in unless it can be read.

Mr. FOUNTAIN. Maybe they can give us another chart.

(The Federal Insecticide, Fungicide, and Rodenticide Act appears in the appendix on p. 218. An organization chart for the Pesticides Regulation Division was subsequently provided and appears in the appendix on p. 297.)

Mr. NAUGHTON. On lindane again, is it not true that the meat inspection division which is now part of C. & M.S., has for some years prohibited the use of lindane in food-handling establishments? So, not only did FDA and PHS raise questions about the safety of this or the appropriateness of using it around food, but even another agency of the Department of Agriculture prohibited its use around food. But still no action was taken—no effective action—until February of this year, sometime after the GAO report, of course.

Going from that, I am really concerned about the problem of getting these substances that are considered dangerous or known to be harmful off the market after the decisions are made.

In the case of thallium, there were reports of deaths or serious harm prior to 1960. In 1960 a change was made in the formula with the hope that it would alleviate the situation. It did not help. In 1965, after who knows how many more deaths had resulted, the registration was finally canceled, but the GAO was able, in 20 percent of the establishments in the Washington area which they sampled, to buy thallium products in January 1968.

While the danger perhaps may not be as great in the case of lindane, it is true, is it not, that you do not register lindane vaporizers, or have not registered them for use in homes, where they would be in the kitchen or around nurseries or elderly people? Is it not also true that lindane vaporizers for use in the home are being advertised in national magazines, and that these products are being sold by the millions for use in the homes right to this day?

Dr. ANDERSON. I do not know about the sale of millions. We are aware of advertising of these products for use in the homes, yes.

Mr. NAUGHTON. I think as recently as 3 or 4 months ago, or perhaps less time than that, a Sunday supplement that is circulated nationally contained an ad for a lindane vaporizer by mail-order sales. Is there not something you can do to stop this?

Mr. MILLER. The most effective action that can be taken to stop this would be cancellation of registration.

Mr. NAUGHTON. There is no registration for this use in the home.

Mr. MILLER. No. Then none of the products could be shipped in interstate commerce.

Mr. NAUGHTON. When a product is being advertised for use in the home with no warning whatever about contamination on food, that may be on the product but not in the advertising?

Mr. MILLER. The problem you are talking about is complicated by the fact that in most of these instances that we are aware of, the interstate shipments themselves have not proved to be illegal. In other words, they have not involved the shipment of a nonregistered product, so that criminal action could not be taken on the basis of the interstate shipment of a nonregistered product.

I might say that some time ago—and by this I mean in the fall of 1967—we became extremely concerned about the advertisements of which you speak, and we started at that time an investigation which included the inducing of samples. What we were attempting to do was, No. 1, to determine whether or not we could build up a criminal file with respect to shipments under these advertisements, bearing in mind, of course, that we do not have any jurisdiction over pure advertising, advertising as such.

Mr. FOUNTAIN. They are under the Federal Trade Commission, is that not true?

Mr. MILLER. Yes, sir. And secondly, we were attempting to determine whether or not we could build up a file which would serve as a basis for the cancellation of the registration.

But as I say, the most effective way to stop this would be a cancellation of registration. If the registration of these products—the lindane pellets—are canceled, then there could be no interstate shipment at all and it would not be possible to advertise the products in this manner.

Mr. NAUGHTON. Have you explored the possibility of using the advertising in conjunction with the shipment? Is not advertising a form of labeling?

Mr. MILLER. It may or may not be. If it meets the definition of accompanying labeling under the statute, then it would be. In order to pursue the theory of which you speak, and construing the advertising to be accompanying labeling—that does not bother me—we would still have to prove that there was a statement which was false or misleading; and in all of the cases where we induce a sample, the product that was shipped in interstate commerce, as I recall, was the product which the advertisement said would be shipped in interstate commerce. The theory would have to be that this was a representation for home use when this particular product had not been registered for use in the home.

Mr. NAUGHTON. Of course, you had a problem because you were registering the product yourselves for use in on restaurants and on a continuous basis where food is? I think some of the ads that have come to our attention appeared in Parade magazine which is nationally distributed on Sundays. Did you at any time contact the publications which were carrying these ads who may have had no idea that such a violation may have been involved in the shipments and called to their attention the provisions of the law and concern about lindane and see whether they wouldn't voluntarily refrain from carrying the ads?

Mr. MILLER. We had several citations on lindane vaporizers and pellets, Mr. Naughton, and I cannot recall whether or not any of those were directed to a mail-order house or not. The reason I give you this type of answer is we have refrained from taking further action in the citation area because of the action which has been taken to cancel registration.

Mr. NAUGHTON. You feel that if the cancellation does succeed and is upheld, then you will have no problem in seizing any shipments of lindane across State lines?

Mr. MILLER. That is correct. And there will also be no question concerning the confusion that results because of the continuous use type vaporizer and the fumigator type.

Mr. NAUGHTON. Let me just read a very short ad:

An electronic bug killer automatically dispenses invisible chemical vapor developed to rid your home of mosquitoes, flies, gnats, spiders, roaches, ants, silverfish moths—even fleas that pester your pets. Just plug it in and forget about bugs all season. One bug killer unit protects average home, has two months' supply of ten lindane pellets.

Nothing on there suggests that it may be dangerous and you should not put it in the nursery or it may leave illegal residues on your food if you have it in the kitchen.

Mr. MILLER. There are some other statements in that advertising that bother me.

Mr. NAUGHTON. Unfortunately, there are a good many people that use products without reading the labels.

Would you perhaps be able to supply some information for the record as to what the situation is in this area, and what you think you may be able to do about it?

(The following statement was subsequently provided:)

The following enforcement actions have been taken with respect to lindane vaporizing units during the first 10 months of fiscal 1969:

1. A recommendation for prosecution has been referred to the Office of the General Counsel of this Department.

2. Notices of contemplated criminal proceedings (citations) have been issued with respect to five lindane vaporizer samples. These samples were of advertised products and were induced by our inspectors, or in one instance, purchased by a consumer. One of these citations involved a mail-order house.

3. Citations have been prepared with respect to nine additional samples. Two of these citations involve mail-order houses.

4. Review has been completed of the investigational material relating to three additional lindane vaporizing unit samples.

As indicated above, enforcement action has been initiated based upon the advertising of the products. The jurisdiction of this Department over economic poison advertising is limited. The Department has no jurisdiction under the FIFRA of advertising as such. However, the Department may take action relative to the interstate shipment of an economic poison where false or misleading claims are made in advertising which constitutes accompanying labeling under the act,

or where claims made in advertising differ in substance from representations made in connection with the registration of the product.

At the time that the decision was made to cancel the lindane registrations, it was also decided that further enforcement actions should be withheld pending the outcome of the registration actions. It is believed that the most effective action which may be taken to prevent further violations in this area is the cancellation of registrations. Additional enforcement action with respect to lindane vaporizers will depend upon the results which are achieved through the cancellation of registration actions.

Mr. FOUNTAIN. Do you coordinate with the Federal Trade Commission in connection with advertising?

Dr. HAYS. Yes, sir.

Mr. FOUNTAIN. Thank you very much, Dr. Anderson and Dr. Hays and your colleagues for coming up, and for your very forthright response to the reports of the Comptroller General and our own questions. We sincerely hope that this public hearing will serve as an incentive to you to appreciate even more seriously the situation, and thus be able to de a better job of correcting it.

We may have you come back for some further questions, but at this point I do not think so.

So the committee stands in recess until the further call of the Chair.

(Whereupon, at 1:15 p.m., the committee was adjourned, to reconvene upon the call of the Chair.)

DEFICIENCIES IN ADMINISTRATION OF FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

TUESDAY, JUNE 24, 1969

HOUSE OF REPRESENTATIVES,
INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, D.C.

The subcommittee met at 10:15 a.m. in room 2203, Rayburn House Office Building, Hon. L. H. Fountain (chairman of the subcommittee) presiding.

Present: Representatives L. H. Fountain, Benjamin S. Rosenthal, Florence P. Dwyer, Clarence J. Brown, Jr., and Guy Vander Jagt.

Also present: James R. Naughton, counsel; William H. Copenhaver, minority counsel; and Morton Myers, staff member.

Mr. FOUNTAIN. Let the committee come to order. Let the record show a quorum is present. Our hearing today is a continuation of an earlier hearing last month in connection with the subcommittee's investigation of the administration of the Federal Insecticide, Fungicide, and Rodenticide Act by the Department of Agriculture and related activities of other Federal agencies.

The Insecticide Act requires that pesticides shipped in interstate commerce must be registered with the Department of Agriculture. Under the law, the manufacturer is required to show that a pesticide is safe and effective before it can be registered. The law provides criminal penalties for interstate shipment of unregistered, adulterated, or misbranded pesticides and authorizes seizure of such products.

Two reports by the General Accounting Office and the previous subcommittee hearing have established the existence of serious deficiencies in the action being taken by the Department of Agriculture to carry out its responsibility to protect the public from hazardous pesticides. At today's hearing we hope to take further testimony concerning this situation and the extent to which action is being taken to correct these deficiencies. In addition to witnesses from the Department of Agriculture, we also have witnesses present from the Food and Drug Administration to testify concerning responsibilities of that agency with respect to pesticides.

Senator Gaylord Nelson of Wisconsin had also planned to present testimony today, but his office has advised us that it may not be possible for him to appear.

I am sorry also that the House will be in session at 11 o'clock, and this may handicap us some, but we will go as long as we can.

We have with us today a number of people from the Department of Agriculture. From the Office of the Secretary, Dr. Ned D. Bayley,

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Director, Science and Education. From the Agricultural Research Service, Dr. George W. Irving, Jr., Administrator; Dr. Robert Anderson, Associate Administrator; Dr. Harry W. Hays, Director, Pesticides Regulation Division; Mr. Lowell E. Miller, Assistant Director for Enforcement, and Mr. Harold G. Alford, Assistant Director for Registration. And from the Office of General Counsel, Mr. Charles W. Bucy, Assistant General Counsel for Marketing, Regulatory Laws, Research, and Operations.

From the Food and Drug Administration, Mr. R. E. Duggan, Deputy Associate Commissioner for Compliance; Dr. T. H. Harris, Chief, Division of Pesticide Registration. Also from HEW, Mr. William W. Goodrich, Assistant General Counsel, Food, Drugs, and Environmental Health Division.

Before we proceed, Dr. Irving, would you care to make any opening remarks? Do you have a statement you would like to give the committee?

Dr. IRVING. I have with me a prepared statement of some 20 pages which we thought might be helpful to the committee.

In light of the previous committee hearing on May 5 and in the light of questions that have been asked of us and responses given since the time of that hearing, we proposed to place in some chronological order the events leading up to and the establishment of the task force which examined the activities of the Pesticide Regulation Division a few years ago, their conclusions, recommendations, and our responses to them.

Second, we proposed to review legislative changes that the Department is in the process of proposing now to strengthen our administration of the Pesticide Regulation Division.

And, third, we proposed to acquaint the committee with a very recent study of the National Academy of Sciences, National Research Council Committee on Persistent Pesticides, their conclusions and recommendations and our observations on them.

That is the sense of the statement that I have, Mr. Chairman. I would be glad to present it to you now or to submit it for the record as you choose.

Mr. FOUNTAIN. Mr. Naughton advises me that the statement, while it would be helpful to us and to the committee, does not directly relate to many of the things we would probably be asking questions about. So, if you don't mind, we would like to receive it into the record for consideration of the full committee. And if you care to make any comments about it or any other comments as a way of preface to our questions, we would be glad to have you do that.

(Dr. Irving's prepared statement follows:)

PREPARED STATEMENT OF DR. GEORGE W. IRVING, JR., ADMINISTRATOR, AGRICULTURAL RESEARCH SERVICE, U.S. DEPARTMENT OF AGRICULTURE

Mr. Chairman, members of the committee, representatives of the Agricultural Research Service appeared before this subcommittee on May 7. Our agency was asked at that time to discuss two areas of our responsibility that had been called to the attention of the Congress by reports from the U.S. General Accounting Office, dated September 10, 1968 and February 20, 1969. Dr. Robert J. Anderson, Associate Administrator, discussed the subjects of the reports: (1) Improving regulatory enforcement procedures involving pesticides, and (2) resolving questions of safety concerning certain registered uses of lindane pesticide pellets. Dr. Anderson reported on our administration of activities in these areas under

the Federal Insecticide, Fungicide, and Rodenticide Act—or FIFRA—and on what we are doing to improve and strengthen these activities.

My associates and I are glad to have the opportunity to come before you today to answer questions and to provide additional information concerning our efforts in ARS to strengthen the administration of pesticides regulation.

I would like to review, first, the establishment of the task force to study the Pesticides Regulation Division, the findings and recommendations of the task force, and what we are doing to implement those recommendations.

ESTABLISHING A TASK FORCE

The discovery and development of pesticides and other chemicals registered under the provisions of the FIFRA increased very rapidly during the period 1945–65. Under the pressure of the large number of new chemicals, plus the complexity of regulating their use to provide for safety and efficacy, the demands upon the Pesticides Regulation Division of ARS also increased. The expended registration and enforcement program of the Division made it necessary to develop ways of meeting the increased workload effectively within budget confines. In response to the need, the Secretary of Agriculture appointed a task force in June 1965 to study the operations of the Pesticides Regulation Division and to submit recommendations based on its findings.

The group consisted of five full-time employees of the U.S. Department of Agriculture and three consultants, representing the National Academy of Sciences, a State government, and an industrial chemist. The representative areas were carefully selected to provide a balance between knowledge of the responsibilities of the Division under study and an informed objectivity regarding the subject matter. Members of the task force were:

Dr. Harry W. Hays, Chairman, Director of the Advisory Center on Toxicology, National Academy of Sciences-National Research Council.
Mr. James T. Caprio, Jr., Office of Budget and Finance, U.S. Department of Agriculture.
Mr. Charles A. Cash, Operations Analysis Staff, Agricultural Stabilization and Conservation Service, U.S. Department of Agriculture.
Dr. T. Roy Hansberry, Agricultural Research Division, Shell Development Company.
Mr. Allen B. Lemmon, Chief, Division of Plant Industry, California Department of Agriculture.
Dr. Wilbur D. McClellan, Crops Protection Research Branch, Crops Research Division, ARS, U.S. Department of Agriculture.
Dr. R. D. Radeleff, Animal Disease and Parasite Research Division, ARS, U.S. Department of Agriculture.
Mr. Kenneth C. Walker, Office of the Administrator, ARS, U.S. Department of Agriculture.

In addition, Mr. Harold G. Alford, Pesticides Regulation Division, ARS, was designated as executive secretary and Mr. George A. Robertson, Office of the General Counsel, as special consultant for the group.

The task force was asked by ARS, with the full support of the Director of Science and Education and of the Secretary, to do the following:

1. Review and evaluate the mechanics of registration, enforcement, management, and organization of the Pesticides Regulation Division in administering the Federal Insecticide, Fungicide, and Rodenticide Act, and to make recommendations for improvement.
2. Review and evaluate the criteria used in determining the safety and efficacy of pesticides and other agricultural chemicals.
3. Review and evaluate work performance efficiency in processing registration applications and recommend changes, including automation, that might be used to improve that efficiency.
4. Review and evaluate the environment for scientists as it relates to initiative and attraction of competent personnel.
5. Explore the adequacies of space, facilities, and financial support of the Division's program.
6. Review the interagency agreement—among the Departments of Agriculture; Interior; and Health, Education, and Welfare—as it relates to the registration of pesticides.
7. Explore ways to improve cooperation between the Pesticides Regulation Division and industry that would be mutually beneficial.

8. Review the procedures for cooperation and liaison with units within the Department of Agriculture and with other Federal and State agencies.

The group held its first meeting July 8 and 9, 1965, at which time they developed lines of inquiry and divided the members into three major subcommittees to allow for an intensive study.

RECOMMENDATIONS AND RESULTING ACTION

On November 19, 1965, the task force presented its report to the Agricultural Research Service. The recommendations of the task force and the actions that we have taken to carry them out are as follows:

1. *Recommendation.*—The Agricultural Research Service should clarify the mission of the Pesticides Regulation Division and keep the Division personnel informed of the objectives.

Since July 1, 1966, the Director of the Pesticides Regulation Division has held biweekly staff meetings to discuss the objectives of the Division in both registration and enforcement as well as any problems that need special attention. The Division has also established regional meetings with their field personnel as part of an information and training program.

2. *Recommendation.*—The Director's Office should consist of a Deputy Director for Registration, a Deputy Director for Enforcement, an administrative officer, an advisory staff, and an Office of Technical Data.

In June 1966, the Director's Office was reorganized to provide for an Assistant Director for Registration, an Assistant Director for Enforcement, an assistant to the Director for Management, an assistant to the Director for Program Appraisal, an assistant to the Director for Cooperative Relations, and an assistant to the Director for Information. The Technical Data Section was established in August 1966. The advisory staff, proposed by the task force, has not been established in that form, but three medical experts have been appointed and do function as collaborators to advise on matters of safety for human health.

3. *Recommendation.*—Under the Deputy Director for Registration, establish a Registration Branch with three sections: (a) a Registration Section, (b) a Renewal Section, and (c) a New Applications Section.

In 1966–67, the registration branch was reorganized to provide for (a) product evaluation staff, (b) Resubmissions Section, (c) Distributors' Labels Section, and (d) Petitions Control Section.

4. *Recommendation.*—Under the Deputy Director for Enforcement, establish an Enforcement Branch having three sections: (a) a Case Development Section, (b) an Investigation Section and (c) a Laboratory Section.

In 1967–68, the Enforcement Branch was reorganized to provide for (a) a Case Review and Development Section, (b) an Inspectional Services Section, (c) a Laboratory Services Section, and (d) a Prosecutions and Imports Section.

5. *Recommendation.*—The Division should publish a manual of instructions for use by the Division staff, outlining the general procedures for registration and enforcement, and criteria to be used in evaluating safety and effectiveness.

In March 1966, the Division began to issue memorandums that disseminate information to the staff on procedures in registration and enforcement. Starting in early 1967, meetings have been held with the safety evaluation staff to review and evaluate data submitted in support of registration. Beginning in October 1968, petitions for a tolerance or exemption from a tolerance under the Food, Drug, and Cosmetic Act, and applications for registration of new chemicals, have been reviewed for safety and effectiveness by the Director and members of the respective review staffs. These memorandums and related documents will serve as the basis for a manual which will be developed for the Division staff.

6. *Recommendation.*—The Division should publish a manual of instructions for use by industry, outlining procedures for registration, types of finished labels, and information needed for various classes of compounds.

Notices from the Division, called PR notices, are issued to members of the industry concerned, outlining changes in registration. These notices will form the basis for a manual of instructions for the benefit of industry.

7. *Recommendation.*—There should be a periodic review of interpretations and the operating personnel should be advised of those changes.

Beginning in latter 1966, interpretations of specific parts of the act have been reviewed periodically at Division staff meetings to determine whether or not revisions are necessary. There are 24 such interpretations that have been published in the Federal Register. For example, it was decided to revise interpreta-

tion 18 concerned with "Warning, Caution, and Antidote Statements on Labels." This revision was published in the Federal Register on April 4, 1969.

8. *Recommendation.*—The Division should insist on having a finished copy of the label to be used on the product before registration is granted.

This recommendation was considered in 1966, but it was decided that the best practical approach was to defer action until the registration branch was adequately staffed and the backlog of registration applications reduced to a workable level.

By July 1 we will be requiring finished labels for all new products before registration and for all products submitted for reregistration. Notice of this policy will be published in the Federal Register and individual notices will be sent to registrants.

9. *Recommendation.*—The Division should make arrangements for space in which conferences with industry representatives can be held in privacy.

In the summer of 1967, the office layout was rearranged to provide each chief staff officer with sufficient space to hold conferences in privacy.

10. *Recommendation.*—The registration section must exercise more rigid controls over the maintenance of files and of confidential information.

In 1967, a special area was assigned for housing the files containing confidential information supplied by applicants or registrants. The files are under the supervision of a clerk, and no one is admitted in the file room except those authorized to have access to the records.

11. *Recommendation.*—Requests to registrants for additional information in support of applications should be made by the Deputy Director for Registration.

Since early 1967, requests for additional information in support of applications have been made by the Assistant Director for Registration.

12. *Recommendation.*—Renewal notices should be limited to one notice 30 days prior to cancellation.

Renewal notices for registration will be sent out, beginning in July, and only one notice will be given.

13. *Recommendation.*—A work measurement system and long-range planning program should be instituted at once to identify future problems and to predict workload and needed resources.

Since 1967, ARS has been working under the Federal long-range planning program, called the planning programing budgeting system. The Pesticides Regulation Division has been requested to develop a program that would be consistent with PPB. The Division has also recently initiated a program appraisal in all field laboratories and stations which will include a study on work measurement.

14. *Recommendation.*—The Division should establish, as soon as possible, an aggressive training and recruitment program. The employees should be encouraged to participate in the incentive awards program.

From 1966 tothe present, approximately 185 out of the 256 people in the Division have taken, or are taking, graduate courses, special courses in instrumentation, in analytical chemistry, as well as managerial and correspondence courses. The Division personnel have been encouraged to participate in the incentive awards program. From 1966 to 1969, 11 quality within-grade increases and four suggestion awards have been authorized. The Division has not developed a recruitment program, but has depended upon the programs conducted by ARS Personnel Division.

15. *Recommendation.*—The enforcement activities should be greatly expanded.

Since 1966, enforcement activities have been greatly expanded. Specific actions taken to strengthen enforcement of FIFRA was the principal topic of discussion during the appearance of ARS representatives before this committee on May 7, and is now a part of the record. Therefore, I will not take the committee's time to repeat the information.

16. *Recommendation.*—The regional chemical laboratories should be consolidated into a central laboratory and a critical review made of the role of the biological laboratories in relation to their importance to the Division.

The chemical laboratories have not been consolidated. We have concluded that the small laboratories are more efficient to operate and require less distance for shipping of samples.

17. *Recommendation.*—Greater cooperation between State and local governments would facilitate the work of the enforcement branch, especially in the area of sampling.

The professional staff of the Pesticides Regulation Division has held eight regional meetings with our field personnel. At each of these meetings, officials of the surrounding States were invited to participate in discussions of recurring State and Federal problems. The Federal inspectors gave detailed demonstrations of methods of sampling, and the analytical chemists discussed official methods of analysis. In addition, both State and Federal officials reviewed the requirements for registration and enforcement as well as what could be done to strengthen operations in these areas.

These meetings have resulted in a better understanding of the responsibilities of State and Federal officials and the need for continued cooperation. The meetings also provided an opportunity to alert the State officials to our recall program and to what they could do to assist us in implementing action taken by our Federal agency.

18. *Recommendation.*—Representatives of the interagency agreement should recommend firm and specific guidelines of responsibility and authority in each of the participating departments. The agreement should be reviewed and, if necessary, revised.

Since 1966, the Pesticides Regulation Division has made a number of changes in our activities taken under the provisions of the interdepartmental agreement. Labels have been transmitted to the participating agencies on a day-to-day basis rather than on a weekly basis as provided in the agreement. We have held meetings with representatives of the Public Health Service, and Food and Drug Administration of HEW and with representatives of the Department of Interior to discuss problem areas and to work out more effective procedures of operation.

Representatives of the three Departments concerned with the agreement have recommended that monthly meetings of working groups be held to determine what additional changes may be needed, including a revision of the agreement itself.

19. *Recommendation.*—Because of the importance of pharmacology and toxicology in determining the safety of all products registered with the Department of Agriculture, we recommend that persons with advanced training in these disciplines be added to the Division.

We have completed our safety evaluation staff, with the exception of the chief staff officer. In regard to this position, we have been unable to find a person who is qualified and available. In the meantime, the Division Director, who is well qualified in toxicology, is giving supervision to this work.

PROPOSED LEGISLATION TO AMEND FIFRA

The Department of Agriculture has taken additional action to strengthen public protection provided by FIFRA through legislation to amend the act. During the 90th Congress, the Department submitted a legislative proposal to strengthen the administration of the act as follows:

(1) Require that every person who owns or operates any establishment in any State, territory, or the District of Columbia, engaged in the manufacture, preparation, propagation, compounding, or processing of an economic poison, register with the Secretary of Agriculture his name and places of business.

(2) Permit inspection of (*a*) establishments in which economic poisons or devices are manufactured, processed, packed, or held for distribution or sale, and (*b*) any means of conveyance being used to transport or hold any economic poison.

(3) Provide that an economic poison shall be deemed misbranded if it is manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered.

(4) Provide that an economic poison is adulterated if the methods, controls, or facilities used for manufacturing, processing, packaging, or holding such economic poison do not conform with good manufacturing practice.

(5) Empower Federal courts to issue injunctions to enforce and restrain violations of the act.

(6) Amend the provisions to add civil penalties.

Similar legislative proposals were introduced in the 89th and 88th Congresses.

No bills have yet been introduced during the 91st Congress to amend FIFRA. The Department is preparing a legislative proposal for submission to the Congress which will include the provisions of the proposal made to the 90th Congress, in addition to some further proposals that appear to be desirable.

COMMITTEE ON PERSISTENT PESTICIDES, NAS–NRC

The Department of Agriculture has taken action to augment the general fund of knowledge concerning pesticides and, thus, to put the Nation in a better position to protect against possible hazards from their use. As an example, in November 1966 the Department requested that the National Academy of Sciences-National Research Council make a study of the impact of persistent pesticides upon the environment. The study was carried out under contract by a "Committee on Persistent Pesticides," established for that purpose.

The committee was made up of 15 representatives of major universities of the country, the chemical industry, and the Public Health Service. Dr. James H. Jensen, president of Oregon State University, served as chairman. The group made an intensive study, including interviews with more than 80 recognized authorities in fields of agriculture, human health, conservation of natural resources and the total environment, food industry, and the chemical industry.

CONCLUSIONS OF THE COMMITTEE ON PERSISTENT PESTICIDES

The committee submitted a report of their findings to me, dated May 27, 1969. Included in the report were the following conclusions:

1. Persistent pesticides are contributing to the health, food supply, and comfort of mankind, but, in the absence of adequate information on their behavior in nature, prudence dictates that such long-lived chemicals should not be needlessly released into the biosphere.

2. Although persistent pesticides have been replaced in some uses and are replaceable in others, they are at present essential in certain situations.

3. No decrease in the use of pesticides is expected in the foreseeable future. On a world basis, increased use is probable.

4. Although the use of DDT has decreased substantially, there was no important change in the use of other organochlorine insecticides in the United States during the 10-year period ending June 30, 1967.

5. Available evidence does not indicate that present levels of pesticide residues in man's food and environment produce an adverse effect on his health.

6. Registration requirements for persistent pesticides appear to provide adequate safeguards for human health, but continuing attention must be given to accommodating new knowledge and insuring against subtle long-term effects.

7. Residues of certain persistent pesticides in the environment have an adverse effect on some species of wild animals and threaten the existence of others.

8. The availability and low cost of effective persistent pesticides have slowed the development and adoption of alternative methods of control.

9. Work on nonchemical methods as alternatives to persistent pesticides has been emphasized in recent years, and continued support for this work is needed.

10. Inadequate attention and support are being given to developing pesticidal chemicals and to improving techniques for using them.

11. Persistent pesticides are of special concern when their residues possess—in addition to persistence—toxicity, mobility in the environment, and a tendency for storage in the biota.

12. A few organochlorine insecticides and their metabolites have become widely distributed in the biosphere, appearing in the biota at points far from their places of application.

13. The biosphere has a large capacity for storage of persistent pesticides in the soil, water, air, and biota, but little is known concerning amounts of persistent pesticides and of their degradation products that are stored in the biosphere.

14. Knowledge is incomplete concerning the fate and degradation of persistent pesticides in the environment, their behavior in the environment, the toxicity of the degradation products, and the interaction of these products with other chemicals.

15. Present methods of regulating the marketing and use of persistent pesticides appear to accomplish the objectives of providing the user with a properly labeled product and holding the amounts of residue in man and his food at a low level. However, they do not appear to insure the prevention of environmental contamination.

16. Public demand for attractiveness in fruit and vegetables, and statutory limits on the presence of insect parts in processed foods, have invited excessive use of pesticides.

17. The national pesticide monitoring program provides adequate information about residues in man and his food, but it does not provide adequate informa-

tion about the environment generally, because it can detect changes in residues only in selected parts of the biosphere.

18. Contamination of the biosphere resulting from the use of persistent pesticides is an international problem. Changes in techniques for using these pesticides and the substitution of alternatives here and abroad are questions of immediate concern to all mankind.

RECOMMENDATIONS OF THE COMMITTEE ON PERSISTENT PESTICIDES

The committee made the following recommendations:

1. That further and more effective steps be taken to reduce the needless or inadvertent release of persistent pesticides into the environment.

2. That, in the public interest, action be increased at international, national, and local levels to minimize environmental contamination where the use of persistent pesticides remains advisable.

3. That studies of the possible long-term effects of low levels of persistent pesticides on man and other mammals be intensified.

4. That efforts to assess the behavior of persistent pesticides and their ecological implications in the environment be expanded and intensified.

5. That public funds for research on chemical methods of pest control be increased without sacrifice of effort on nonchemical methods.

6. That the present system of regulation, inspection, and monitoring to protect man and his food supply from pesticide contamination be continued.

7. That the objectives and procedures of the national pesticide monitoring program be reviewed and that the feasibility of obtaining data on quantities of persistent pesticides in the biosphere be studied.

CONCLUSION

The NAS–NRC Committee's appraisal of the situation relating to persistent pesticides appears to be reasonable and balanced. Its conclusions and recommendations imply some changes in Department programs that will require some additional time for full evaluation.

In conclusion, I believe that my statement as a whole points up the fact that we are dealing effectively with the problems of pesticides regulation. I have also indicated that there is more to be done, particularly in the area of enforcement. We intend to continue making improvements through the 1971 budget process, through proposals to the Congress for additional legislation, and through our proposed organizational changes in the Pesticides Regulation Division. Action on the 1970 budget will determine the extent to which we can implement some of these changes more immediately.

Mr. Chairman, that concludes my statement. My colleagues and I will be glad to answer questions at this time.

Dr. IRVING. Very good, sir. I would like to say just this: The burden, workload, great proliferation of the number of chemicals that were being offered for registration several years ago put increasing pressure upon the Pesticide Regulation Division to handle them. There was evidence of delays in the registration of these chemicals.

In response to a need to examine the procedures of the Division the Secretary of Agriculture appointed a task force that was chaired by Dr. Hays, who is here at the table with me, now the Director of the Pesticides Regulation Division, and a number of other people inside and outside the Department, to advise us on operations in that Division. That they did. They made certain recommendations which have since been taken under advisement and most of them have been followed to strengthen the operation of the Division.

We are now in vastly better condition with respect to registration in that Division than we were prior to that time. We also have strengthened our enforcement activities as a result of the recommendations of that report. We do recognize some deficiencies in the current legislation under which we operate.

We have in several Congresses past submitted proposals for amendment of the Federal Insecticide, Fungicide, and Rodenticide Act. No action has been taken to date.

Mr. FOUNTAIN. Who were those proposals submitted to—proposals or amendments?

Dr. IRVING. These would be a part of the Department's—the Secretary's—legislative program submitted to the Congress as proposals of the Department.

Mr. NAUGHTON. Dr. Irving, have any legislative proposals in this area actually been submitted to the 91st Congress?

Dr. IRVING. The current Congress?

Mr. NAUGHTON. Yes.

Dr. IRVING. No, sir; not yet.

Mr. NAUGHTON. Then you don't expect any action this session, do you?

Dr. IRVING. It is conceivable we could still get action this session. But as you well understand, such proposals have to be cleared through the Executive, including the Bureau of the Budget, before they can be submitted. That is the current status.

Mr. NAUGHTON. Do you feel that the lack of the additional legislative authority you eventually may seek is the heart of the problem relating to these deficiencies in administration or is this just something that would be of some additional help?

Dr. IRVING. I think it contributes heavily to the total problem. I don't think new legislation will correct some of the things for which we have been criticized.

Our major lack I think, Mr. Naughton, has been funds and the personnel ceilings that have prevented us from fully staffing as we would hope to do eventually, the various parts of the Pesticide Regulation Division.

I think you are perhaps familiar with some of the items in the legislation proposed. We need authorization to inspect and to license manufacturers and distributors of these chemicals, access to their enterprises. This would help us very much, I believe, in controlling the economic poisons, so-called, in interstate commerce. I don't think it would correct all of our problems but it would be a distinct help to us.

Mr. NAUGHTON. For some 20 years almost I think the Agricultural Research Service, Pesticide Regulation Division, had the authority to examine records of manufacturers to determine where hazardous or potentially hazardous chemicals have been shipped in order to get them off the market.

Prior to the last few months did you ever once exercise that authority?

Dr. IRVING. To what extent have we exercised that authority prior to the last few months, Dr. Hays?

Dr. HAYS. I think we have, Mr. Naughton, on several occasions exercised this authority in our seizure actions and voluntary recall on the part of the industry to withdraw materials from the market.

Mr. NAUGHTON. Prior to the last few months, Doctor?

Dr. HAYS. Yes.

Mr. NAUGHTON. Would you provide a list of every time, prior to 18 months ago, that you exercised this authority? There may have been a few times. I am not aware of any.

Dr. HAYS. We would be glad to provide it.

(The following statement was subsequently submitted:)

In addition to those cases listed in a letter to Victor L. Lowe from R. J. Anderson dated May 22, 1968, a copy of which was presented in connection with the previous hearing before the Subcommittee on Intergovernmental Relations House Committee on Government Operations, May 7, 1969, a further review of our records indicates that in 1962 on the basis of nonregistration we intercepted and seized interstate shipments of "Steri-Fleece," a laundry product containing (3,4,4-trichlorocarbanilide) which caused methemoglobinemia when diapers laundered in the product were used on premature infants. Representatives of the Division examined the company's records to determine where the product was shipped. Calusa Chemical Co., the manufacturer, recalled all other outstanding merchandise which was not seized.

On two other occasions inspectors of PRD visited the Chipman Chemical Co., of Portland, Oreg. Once on February 2, 1963, to examine the records regarding a product containing "Rotenone," which was contaminated with DDT. The other instance was in February 1965. This involved two products, each an insecticide which was adulterated with a herbicide. Our inspector confirmed that in each instance the company's records showed that outstanding stocks had been recalled.

Prior to May 22, 1968, we had not routinely examined shipping records of companies.

Mr. NAUGHTON. Dr. Irving, do you really think that some additional legislative authority that you have sought in past Congresses and may wind up seeking in this Congress is the heart of the problem? Have you read the record of the previous hearings and the GAO reports?

Dr. IRVING. Yes, sir.

Mr. NAUGHTON. Aren't there a great many things there that don't relate to lack of personnel but relate to a lack of appropriate use of personnel and authority that you have?

Dr. IRVING. I will concede that. There are some things that we should have done better and are now doing better than we did in the period covered by these reports.

Mr. NAUGHTON. Do you think you have the situation essentially in hand at the present time? Are you satisfied that there is nothing, significant, more to be done?

Dr. IRVING. I am never satisfied. I merely say we are in better shape than we were at the period when the General Accounting Office made their study.

Mr. FOUNTAIN. Dr. Hays, at our last hearing you were asked to supply information for the record as to what arrangements you had for receiving reports on pesticide poisonings, both from Federal sources and from State and local sources and how well you thought these arrangements were working.

The answer supplied for the record stated, and I quote, "The reporting system appears to be working very well." What is the basis for that conclusion?

Dr. HAYS. Mr. Fountain, I think our system of reporting prior to the registration of any product is, in my opinion, fully satisfactory. I think, as I mentioned to the committee at our last hearing, we have in every submission for the registration of an economic poison the requirement under the act that the registrant shall provide whatever information is deemed necessary by the Secretary, for both effectiveness and safety.

Therefore, it is the responsibility of the industry to provide this kind of information. In doing so, we set down our requirements of

the type of data that we think is essential to demonstrate the effectiveness of any given product.

Now, this comes to us in an array of forms. The industry may have the laboratory facilities and the scientific personnel to this type of work.

Mr. FOUNTAIN. Are you talking about registration now, Dr. Hays?

Dr. HAYS. Yes.

Mr. FOUNTAIN. I am talking about accident reporting.

Dr. HAYS. I am sorry. I misinterpreted your question. Our accident reporting has been dependent entirely upon the information that is brought to us by a variety of sources, either by radio, by newspapers, by the State officials, by whatever means possible, and when we receive this information we make an investigation.

Our inspectors, which I mentioned before at the committee meeting—we have but 26 inspectors for this job. We attempt to find out the reasons for the particular accident, to determine first whether the product was in compliance with the act, whether the directions for use were adequate and, if complied with, would have prevented the accident, or whether the directions for use were such that they might be altered to give greater protection.

We think that this system of reporting is good. It is not fully adequate. We do need more people in the field to do this kind of work.

Mr. FOUNTAIN. Approximately how many reports do you receive annually on pesticide poisoning?

Dr. HAYS. I would have to ask one of the members of the staff who is here.

Mr. FOUNTAIN. I would be delighted for you to call on anybody.

Dr. HAYS. Mr. Dellavecchia, how many accidents, roughly, do we have annually?

Mr. FOUNTAIN. Reports of accidents.

Mr. DELLAVECCHIA. I would hazard a guess here. Last year we investigated 151 accidents. Now we endeavor to investigate all we hear about, so I would hazard a guess that the number of reports we received was approximately, say, 150 to 175. In other words, as we receive the reports of the accidents we do endeavor to investigate them.

Mr. FOUNTAIN. How does that number compare in your opinion with the total number of pesticide poisonings occurring every year?

Dr. HAYS. I don't believe there is any way in which we can really ascertain that figure. I have seen figures that are rather, in my opinion, astronomical. And I certainly don't believe that one report of some 20,000 accidents is anywhere near correct. We are sure we don't receive all reports of all accidents, but I believe we get a fair share of those involving economic poisonings.

Mr. FOUNTAIN. Do we have any figures from the poison control center?

Mr. NAUGHTON. Yes, but first may I ask Dr. Hays: You think the 150 poisoning reports or 175 that you receive annually is a fair share of the total number of pesticide poisonings?

Dr. HAYS. I think it is a reasonable estimate, although if our system of reporting is anywhere similar to that of the poison control center, then of course it would not be representative.

Mr. FOUNTAIN. Is that for the whole Nation? 150 to 175 for the whole Nation?

Dr. HAYS. Those involving pesticides, yes.

Mr. NAUGHTON. We do have figures from the poison control centers.

I might indicate the poison control centers were originally set up by the Public Health Service and it is a voluntary network which has a headquarters unit in Washington and has units throughout the country generally affiliated with hospitals.

The purpose of the centers is to obtain information concerning components of various compounds which are in general use, particularly in households throughout the country and to keep available information concerning the antidotes that should be used in the event of poisonings resulting from those compounds.

Their purpose is not to gather information. At least their basic purpose is not to gather information as to the number of poisonings from various causes, but when they get a call from someone, in the event of a poisoning, they make a report which does include, insofar as they get the information the nature of the product responsible for the poisoning.

The poison control centers receive, it is our understanding, something in the neighborhood of 5,000 reports of poisonings by pesticides annually, of which approximately 4,000 involve children under 5.

The poison control center people advise us that in their opinion the total number of poisonings is actually 8 to 10 times greater than the number of reports they receive because they receive only a small fraction.

From other sources also, the best information we could obtain would indicate that the number of pesticide poisonings is somewhere in the area of 50,000 annually.

Mr. FOUNTAIN. Were you aware, Doctor, that the poison control centers do receive a substantial number of reports each year on pesticide poisons?

Dr. HAYS. Yes, sir.

Mr. FOUNTAIN. Do you customarily obtain from the poison control centers data reported to them as to the particular pesticides involved in poisonings?

Dr. HAYS. Mr. Chairman, we have been routinely checking with the poison control center, with Dr. Verhulst, to review the records on pesticides accidents.

Mr. FOUNTAIN. How long have you been doing that?

Dr. HAYS. I would say in the past year.

Mr. FOUNTAIN. What about prior to that time?

Dr. HAYS. I am not sure we made ourselves available of this particular service.

Mr. NAUGHTON. Dr. Hays, aren't there computer runs made by the poison control centers which list each accident and the type of poison? Are you familiar at all with that?

Dr. HAYS. I am not aware of that.

Mr. NAUGHTON. You are not aware that a considerable amount of data is available which, it is our understanding, is not being requested by Agriculture Research Service, though we understand on occasion when you are investigating a particular pesticide you may ask the poison control center whether or not they have had accidents reported or how many they had from a particular pesticide. Do you—

well, it is obvious you weren't aware they receive about 5,000 reports a year.

Dr. HAYS. That is correct.

Mr. FOUNTAIN. How many of the 150 or so reports, 175, whatever the figure was, you receive and investigate, concerning pesticide poisonings involve human beings?

Dr. HAYS. I would have to—let me check again with Mr. Dellavecchia.

Dr. IRVING. These statistical figures I am hearing—I am a bit confused by them. I know the ones Dr. Hays is reporting are incidents which may involve many people in each of the accidents. I think those that Mr. Naughton is mentioning are individual human cases, are they not?

Mr. NAUGHTON. I am not certain about that. At least one human is involved in each case.

Mr. FOUNTAIN. I think Dr. Irving raises an important question. When you refer to these 5,000 pesticide poisonings anually, are there 5,000 individuals or 5,000 incidents, 5,000 reports, and do your reports involve a number of individuals, each of those reports?

Maybe we should get that straight for the record.

Dr. HAYS. Of the 151, 52 of these involved humans.

Mr. FOUNTAIN. About a third.

Dr. HAYS. Yes.

Mr. NAUGHTON. What did the rest involve?

Dr. HAYS. Domestic animals, crops, fish and wildlife, water—pollution of water, and the rest, I would say, undetermined causes.

Mr. NAUGHTON. You had cattle, too, and farm animals. Aren't those probably the bulk? If you had a single large category there, wouldn't it be farm animals?

Dr. HAYS. Mostly.

Mr. NAUGHTON. Out of those 52 incidents involving humans, what is the total number of humans involved?

Dr. HAYS. 163.

Mr. NAUGHTON. Now the poison control centers, Mr. Dellavecchia, they don't keep records on animals, do they? Aren't all their cases humans?

Mr. DELLAVECCHIA. I don't know, sir.

Mr. MYERS. Yes.

Mr. NAUGHTON. Mr. Myers tells me they are all humans.

Mr. FOUNTAIN. Of course, Doctor, you have no way of being sure that a lot of children are not being poisoned unnecessarily, if you don't have a comprehensive system for obtaining poison reports, do you?

Screening reports and registrations will help but many of the 50,000 or so pesticides poisonings annually could be prevented, I believe, if accident patterns quickly become apparent, is that right?

Dr. HAYS. That is possible, sir.

Mr. NAUGHTON. Isn't it apparent that 162 human incidents that you get on a yearly basis is only a very small fraction of the actual number of pesticide poisonings to humans?

Dr. HAYS. That is a matter I think we don't have actual data on.

Mr. NAUGHTON. You told us a couple of weeks ago your accident report system is working very well. Do you still think it is?

Dr. HAYS. The trouble with these records are that every accident, whether it be simply swallowing something that is inert and the housewife takes the child to the hospital, becomes a hospitalization, so it is not a very accurate record of what we are referring to as actual poisonings.

Mr. NAUGHTON. How many of those 4 to 5,000 cases a year that they receive result in death?

Dr. HAYS. I have no figure on that.

Mr. NAUGHTON. So, you are not in a position to——

Mr. ROSENTHAL. How can you operate without knowing these figures? How can you even continue to certify pesticides without knowing these figures? The first thing I would do is spend a week and find out how these figures jive with Poison Control and what I have and the rest of us. It sounds shocking when you say to him "I don't know how many of those involve death."

Dr. HAYS. This is very difficult data to come by. It wasn't until a few years ago that the Poison Control Center was established—they are now organized throughout the various States and it is conceivable that one could make a very careful check, but here again the records are still not as adequate as they should be.

Mr. ROSENTHAL. Did you ever ask them how many involve death?

Dr. HAYS. The total number?

Mr. ROSENTHAL. For last year. How many of the 5,000 cases involve death?

Dr. HAYS. I don't think we asked that question.

Mr. ROSENTHAL. It would seem to me it is the most elementary thing to do. Why don't you call them up and ask them?

Dr. IRVING. That, we can do, Mr. Rosenthal, and we should. We should have this figure. I am sure it must be a matter of record.

Mr. ROSENTHAL. I don't know how the chairman feels. I think it is insulting to this committee for you to appear before us and not have that information.

Mr. FOUNTAIN. I think the important thing is whether or not they have been getting this information before they appeared before the committee. I agree with Mr. Rosenthal. I think——

Mr. NAUGHTON. Doctor Irving, what is your opinion as to whether the accident reporting system is working very well?

Dr. IRVING. The accident reporting system in ARS? I think in the time that we have been operating, and it is a short time, that it is working very well. I think the reports of incidents that come to our attention through the means Doctor Hays said are representative of what is happening in the United States with respect to pesticides. I would like to know myself, as a result of the discussion here this morning, the number of people that are involved in contrast to those that we are talking about in the records of the Poison Control Center. I would like to know how many of those in the Poison Control Center records are false alarms—I am sure many are—and I would also like to know the answer to the question Mr. Rosenthal asked us. How many are deaths. My impression from all I have seen otherwise is that the number of deaths from pesticides is very, very small.

Now, I can't give you a definite figure on that, but I would just guess here that of these 4,000, if that is an accurate figure, that very, very few of them would be deaths.

Mr. NAUGHTON. Isn't that a subject that a man in charge of a regulatory agency shouldn't be guessing about after 20 years?

Mr. ROSENTHAL. That is up to us to decide.

Mr. FOUNTAIN. That is a matter of opinion. I think the important question is: Have you been able, or would you have been able, had you taken the necessary steps to obtain the information which you now say is available?

Dr. IRVING. Yes, sir. I think the information—we could avail ourselves of the information that exists and we should have.

Mr. NAUGHTON. Let me ask Mr. Dellavecchia: How many of the 162 humans in the cases you investigated died?

Mr. DELLAVECCHIA. Eighteen.

Mr. ROSENTHAL. Eighteen deaths?

Mr. DELLAVECCHIA. Yes.

Mr. ROSENTHAL. In the cases you have reported, one of you two gentlemen said you didn't think there were many deaths.

Dr. IRVING. I said that.

Mr. ROSENTHAL. Eighteen is not many?

Dr. IRVING. It is a very dangerous ground to get on to minimize or maximize figures. I won't do it. I think 18 deaths is very serious. Eighteen deaths is most serious. I would not minimize it.

Mr. FOUNTAIN. Doctor Hays——

Mr. ROSENTHAL. Let me pursue this. Is there an intergovernmental or interdepartmental body that coordinates your efforts and Public Health Service efforts in trying to make accident reporting more efficient so that throughout the entire government everybody knows what the figures are?

Dr. IRVING. There is, Mr. Rosenthal, an interdepartmental Federal Committee on Pest Control which has a subcommittee which concerns itself with information quite like this, and Dr. Anderson, who is current Chairman of that Committee, can answer better than I.

Dr. ANDERSON. Yes, sir. The Federal Committee on Pest Control does have a subcommittee concerned primarily with developing and coordinating an accurate, reliable accident investigation system which would bring together the reporting systems of Public Health, reporting systems of Interior, the reporting system of the Department of Agriculture, where they are meshed in together and would result in obtaining an accurate report of the accidents as is possible to get.

Mr. ROSENTHAL. When was their last report issued, Dr. Anderson?

Dr. ANDERSON. Just recently. They have reported to the parent committee that they had discussions—this is a recently, annual, appointed subcommittee—and they are working together in developing a system. We don't have, yet, a report of the total accidents from all of these different agencies.

Mr. ROSENTHAL. With all the resources you have, you still don't know the number of pesticide accidents for last year, for example?

Dr. ANDERSON. Yes; we do. There is a report prepared by, I believe, the Poison Control Center of PHS. I believe it is a quarterly report. We get that and we do have it in our records, the number of accidents reported. We include along with that the accident report that we have and we compile that into a report of the Department.

Mr. FOUNTAIN. Do you know of a comprehensive system for receiving reports of poisoning?

Dr. ANDERSON. As I said, this subcommittee is charged with developing that comprehensive system. It is not fully operative yet.

Mr. FOUNTAIN. But you haven't had it until recently.

Dr. ANDERSON. No.

Mr. FOUNTAIN. Can you explain why?

Dr. ANDERSON. I wouldn't want to hazard a guess there. Each agency has had a certain system of their own. It just hasn't been coordinated up to this time.

Mr. FOUNTAIN. There had been no central reporting agency?

Dr. ANDERSON. No.

Mr. FOUNTAIN. Whose responsibility is it?

Dr. ANDERSON. The Federal Committee on Pest Control has taken over this responsibility of developing a coordinated national accident investigation system.

Mr. FOUNTAIN. But you do have to pass judgment on the pesticides. You have to approve them?

Dr. ANDERSON. Yes.

Mr. FOUNTAIN. One of the bases for approving pesticides is such information as you can get concerning its effectiveness and how it affects human beings and animals?

Dr. ANDERSON. Yes. I might add, Mr. Chairman, that it has been approximately 5 years ago that in the Department of Agriculture's Plant Pest Control Division we set up a pesticide accident investigation system.

We use all of the USDA agencies throughout the country. We informed them of this system. We gave them the name of the Plant Pest Control Division's employee in each State to contact whenever they received a report of an accident involving pesticides, fish kills, human deaths, livestock and pet injuries, and crop damages, and it is their responsibility to investigate it and determine the cause of it. We do have records to that effect.

Mr. ROSENTHAL. Let me ask you if you can clarify a question in my mind. I have a memo dated May 12, 1969, subject, pesticide accident-incident situation report. Memorandum to W. C. Shaw, chairman, FCPC Subcommittee on Pesticides Marketing and Disposal. It says here:

> Conferences with personnel from USDI, DOT, DHEW, and DOD, indicated that no overall comprehensive coordinated system for investigating, tabulating, reporting, and exchanging information on pesticide accidents-incidents were in operation (February to March 1969).

What does that mean?

Dr. ANDERSON. That means that there was no comprehensive coordinated system, and the FCPC has assigned this task force the responsibility of determining what is in existence and what needs to be done to develop a coordinated and comprehensive system.

Mr. ROSENTHAL. You told me earlier there were statistics available throughout the Government——

Dr. ANDERSON. There are, by individual agencies. But they are not brought together as a comprehensive system.

Mr. ROSENTHAL. When, in your judgment, will it be that anyone within the Government can get a compilation of last year's pesticides or economic poison accidents?

Dr. ANDERSON. I haven't checked with the subcommittee recently to determine what their estimated timetable is, sir, but it should be within a 6-month period.

Mr. ROSENTHAL. Do you think maybe you ought to suspend registration of all these items until you can get those figures?

Dr. ANDERSON. No, sir; I don't.

Mr. ROSENTHAL. That is too radical an idea?

Dr. ANDERSON. I wouldn't say it in that regard. I would say if we had evidence to show that all these accidents were due to improper registration, I think we would have a basis for restricting registration. But many of these—I would say the majority of the—are unrelated to the registered use.

Mr. ROSENTHAL. But they are related to the use.

Dr. ANDERSON. I would say misuse.

Mr. ROSENTHAL. If the average citizen can misuse, maybe they ought to be taken off the market—like cigarettes. [Laughter.]

Dr. ANDERSON. No comment, sir.

Mr. FOUNTAIN. Dr. Hays, at our last hearing we discussed examples of contradictory or confusing labeling of pesticides which had been approved by the Pesticides Regulation Division. For example, labels for lindane pellets warned against contamination of food, but directions for use called for installation of continuous vaporizers in restaurants and foodhandling establishments, which was almost certain to contaminate food, as your recent tests indicated.

What procedures, if any, do you have to insure that contradictory or confusing labeling, particularly with respect to questions of safety, is not approved and that label directions and warnings are clear and understandable?

Dr. HAYS. Well, Mr. Chairman, we have on our labels that when using pesticides every precaution be taken to protect the food and not to apply it directly to the food. In other words, the label may say to protect or cover the food when applying a pesticide in this area.

Mr. FOUNTAIN. Would you say this example I used of labels for lindane pellets is an unusual one, where directions called for the installation of vaporizers in restaurants?

Dr. HAYS. I agree.

Mr. FOUNTAIN. Yet has a warning against contamination in food?

Dr. HAYS. That is right.

Mr. FOUNTAIN. What effort, if any, is made to insure that all warning statements and cautions, where necessary, are integrated in the directions for use so that an unwary user will not be exposed to needless hazards if he follows the directions and fails to read the warnings?

Dr. HAYS. Mr. Chairman, I think that our labeling, our directions for use, are reviewed with the intent of trying to state as clearly as possible to the user the hazards associated with a product's use and if used in accordance with the directions will not produce any injury in that use.

We continue to revise the labeling wherever we suspect that there may be an opportunity for some misuse.

Mr. NAUGHTON. Dr. Hays, do you have a specific procedure to insure that the warning statements and cautions are also integrated in the directions for the use so that whether the user reads one or the other or both he will still not be misled?

Dr. HAYS. Well, Mr. Naughton, again we try to point out to the user in the precautionary statements the things that he must do to prevent any injury to the user.

In addition, of course, we have a campaign on the radio and on television and in our pamphlets in the Department of Agriculture pointing out the proper use of pesticides, to read the label before using it at any time.

Mr. NAUGHTON. I appreciate that, but you have two sections on the label. One includes warnings. It tells the user what to beware of. "Don't inhale this substance. Don't leave it where children can get it." Things like that.

On the other side of the package, you have directions for use. Do you check the directions for use against the warnings so that the directions for use don't tell the man to do something that the warning tells him not to do?

Dr. HAYS. I think in most cases this is very carefully checked.

Mr. NAUGHTON. In most cases?

Dr. HAYS. There may be, at times, an inconsistency where you say avoid inhalation, but if you spray it in the room, obviously you have to inhale it. But we are saying avoid prolonged inhalation or direct inhalation. Some may construe this to be an inconsistency. How can you spray it and still not inhale it?

Mr. NAUGHTON. You can put on directions for use, "don't use for over so many minutes of time."

Dr. HAYS. That is correct. We say avoid prolonged inhalation.

Mr. FOUNTAIN. Are you confident that the products being approved for registration at the present time are being screened carefully enough so that obviously contradictory labeling such as Mr. Naughton is talking about would no longer get by?

Dr. HAYS. I think we are doing the best job possible, Mr. Chairman, in screening not only the labels but in reviewing and reviewing again, all the data submitted with that particular application, to make certain that the precautionary labeling is consistent with the data and that the directions for use are adequate.

Mr. FOUNTAIN. How much material do you have to review?

Dr. HAYS. There are two types of material. First the data submitted with the application. That's the first review. It is on this basis, sir, that you determine what goes on this label.

Then, after the review of the data we then review carefully the proposed directions or proposed labeling.

Mr. FOUNTAIN. When you say "we" who does that in the agency?

Dr. HAYS. Our scientific review staff.

Mr. FOUNTAIN. How many people do you have doing that?

Dr. HAYS. We have about 50 or 60 people reviewing labels in the various disciplines.

Mr. FOUNTAIN. Then you're confident that at the present time, products submitted for registration are being screened carefully?

Dr. HAYS. Yes, sir. I am fully convinced they are being screened very carefully.

Mr. FOUNTAIN. How long have you been doing that?

Dr. HAYS. We have been doing this since 1966. July 1 is when I came to the Division.

Mr. FOUNTAIN. Mr. Naughton, you might read some pertinent excerpts from a label which was accepted by PRD for registration on May 12, 5 days after our last hearing, as an example of the sort of thing that can and does happen.

Mr. NAUGHTON. Mr. Chairman, this is a labeling for concentrated insecticide, fly and roach spray, manufactured by the Hysan Products Co. of Chicago.

The cautions include the following statements:

Use in well ventilated rooms or areas only. Always spray away from you. Do not stay in room that has been heavily treated. Avoid inhalation.

On the other side, the directions for use start out in this manner:

Close all doors, windows, and transoms. Spray with a fine mist sprayer freely upwards in all directions so the room is filled with the vapor. If insects have not dropped to the floor in 3 minutes repeat spraying, as quantity sprayed was insufficient. After 10 minutes doors and windows may be opened.

Mr. ROSENTHAL. If there is anybody around to open them. [Laughter.]

Mr. FOUNTAIN. Any comment on that particular label?

Dr. HAYS. I have no comment. I would have to study the label carefully.

Mr. FOUNTAIN. Mr. Naughton, are there any other directions that would in any way moderate that statement, or explain it or explain away the seeming inconsistency?

Mr. NAUGHTON. No. If the user starts out at the top of the label there and reads the directions, when he gets in that room he closes all the doors and windows and starts spraying.

I think you're lucky if you can get people to read half the label, let alone the whole thing.

Mr. FOUNTAIN. I think when the average citizen buys this sort of thing, he dosen't read the labels, but if it's on the market he assumes that it's good for the purpose for which it's intended, and he goes about the job of trying to kill the roaches by whatever method he heard about.

I sometimes wonder how many people do read labels. Yet you have to have the pesticide and you've got to give instructions. Otherwise they do cause serious harm.

Mr. NAUGHTON. In this case the user might be better off if he didn't read it.

Mr. FOUNTAIN. That's probably true.

Dr. Hays, in its investigation, the subcommittee staff has reviewed a comparatively small number of labels, but out of that small number we found several on which the directions for use obviously were contradictory to the safety warnings.

Can you think of any good reason why we should not be concerned that hundreds or possibly thousands of approved labels out of some 45,000 products on the market are not just as obviously contradictory?

Dr. HAYS. I would be very much concerned, sir.

Mr. FOUNTAIN. Now, I would like to ask a few questions concerning products which are marketed over the objections of other agencies. It looks like we are still getting some examples today of the extent to which a number of agencies are engaged in some of the same things and maybe a lack of coordination between various agencies.

Dr. Hays, at our last hearing, I believe Mrs. Dwyer, our ranking minority member, asked how many products were presently being marketed under ARS registration even though some other Government agency had raised a question as to their safety. You responded there were some 45,000 registered products and indicated that you thought there were only maybe a half dozen as to which safety questions had been raised.

Is it still your opinion that only about half a dozen of 45,000 registered products were objected to by the Public Health Service?

Dr. HAYS. Mr. Chairman, when I answered that question I was referring to a group of compounds, and not products.

For example, in the information I have transmitted to your committee, there are, I think, only six main chemicals, groups of chemicals, that are involved. But this group of six or eight may involve several hundred products.

The six, again, refers to a particular chemical making up a number of products.

Mr. ROSENTHAL. How many products in all would be within that six or eight groups?

Dr. HAYS. About 252, I believe.

Mr. FOUNTAIN. I believe you have admitted in some material you supplied for the record that the Public Health Service objected to at least 270 products in a 15-month period.

Mr. NAUGHTON. I think it's about 250. That covers a 1-year period, I understand, is that correct?

Dr. HAYS. That's correct.

Mr. NAUGHTON. 252 for 1 year, and the products stay on the market for 5 years before they have to be reregistered?

Dr. HAYS. That's correct.

Mr. NAUGHTON. So would it be fair to presume perhaps this total number is five times the one you speak of?

Dr. HAYS. I doubt that, because they would have repeated themselves in the previous years. Those same materials.

Mr. NAUGHTON. If we are talking about products—you used the total of 45,000 products. You compared that with a half dozen, which would lead the subcommittee to believe there was no great problem in this area.

But in actuality there were 252 products in 1 year, and the registration cycle is 5 years, so that we really apparently have quite a number of products on the market that were put there over the objection of the Public Health Service.

Isn't that true? Many more than half a dozen.

Dr. HAYS. Oh, yes.

Mr. ROSENTHAL. Do you go ahead and register products even though Public Health Service objects?

Dr. IRVING. Yes, sir, we do.

Mr. FOUNTAIN. What was that question?

Mr. ROSENTHAL. I asked if they go ahead and register products even though PHS objects. The answer was "yes."

Could you give me briefly your logic in doing that?

Dr. IRVING. We are required under the three-way agreement to submit to the Department of Health, Education, and Welfare and the Department of the Interior, requests for registration to get their advice where it is specific, and it can be judged along with other evidence that

we have from the one submitting the chemical for registration, and if it is indicated that we shouldn't register it, we don't register it.

Where the advice we are getting is not specific, we have nothing specific to consider along with other evidence we have available from the literature and our experience. We believe, as the one who is charged with administration of the act, our judgment should prevail and the action we take is to register in the absence of evidence to indicate it shouldn't be.

Mr. ROSENTHAL. I'm reading from page 14 of the GAO report, dated February 20, 1969. The report says that in February and April of 1967, a company submitted labeling and revised labeling to ARS in connection with an application for registering lindane pellets. On April 28, ARS referred the application to PHS for comments with respect to the safety of the product.

On May 5, 1967, Public Health Service informed ARS that it could not recommend registration of the product because the design and usage pattern provided for the continuous vaporization of lindane in food handling and so forth.

Subsequently, ARS accepted lindane pellets for registration on a continuous basis June 19, 1967. That's the kind of thing you mean, where PHS wasn't specific enough in their objection?

Dr. IRVING. Yes, sir.

Mr. ROSENTHAL. Do you see your mission in Government as getting registration of economic poisons on the market or protecting the American consumer from accidents or injury from economic poisons? Which are your missions?

Dr. IRVING. Our mission is to administer the Federal Insecticide, Fungicide, and Rodenticide Act, and our goals are to register only those compounds that are safe and effective.

Mr. ROSENTHAL. When the Public Health Service suggests to you, even though not in the precise language you would like, that they find something, that they are wary of something or urge caution on something, nonetheless, in spite of that position, you go ahead and register? That seems unusual to me.

Dr. IRVING. The alternative is to not register when there is any objection. I suspect that's right.

Mr. ROSENTHAL. Isn't a Government agency a responsible group? You already have 45,000 products on the market. If you held up on a few more for awhile, it wouldn't be any great damage to society.

Dr. IRVING. Our basis for holding up would be what?

Mr. ROSENTHAL. Objection of the PHS. They are not a private citizen who irrationally comes in and complains about something.

Dr. IRVING. No, sir. I don't mean to bicker on this, Mr. Rosenthal, but when we have no basis whatsoever for the objection raised, it's impossible for us to evaluate that objection.

Mr. ROSENTHAL. Have you ever gone to them and said either stop giving us these evasive objections, or be precise in your recommendations?

Dr. IRVING. Repeatedly.

Mr. ROSENTHAL. What do they say to that?

Dr. IRVING. We have no specifics from the PHS.

Mr. ROSENTHAL. Is there any structure in the Government that someone else can oversee this dispute between you two groups?

Dr. IRVING. Yes, sir.

Mr. ROSENTHAL. Who is that person?

Dr. IRVING. The Secretary of Agriculture.

Mr. ROSENTHAL. Have you ever brought this problem to him?

Dr. IRVING. Not yet.

Mr. FOUNTAIN. You mean he and Secretary Finch couldn't get together to work this out?

Mr. NAUGHTON. The interagency agreement has been in effect since 1964, hasn't it, approximately?

Dr. IRVING. 1964.

Mr. NAUGHTON. Doesn't it require that if there are unresolved questions, for instance between two agencies such as ARS and the Public Health Service, as to the safety of these compounds, that the questions are to be resolved within 2 weeks and if they are not resolved within 2 weeks, that they shall then go to the Secretary of the Department concerned?

Dr. IRVING. I believe that's the language; yes, sir.

Mr. NAUGHTON. Now, we just heard testimony there were 252 products in 1 year's time alone to which PHS objected. Did the Public Health Service withdraw its objections to those 252 products?

Dr. HAYS. Mr. Naughton, again I would repeat that of the 252 products involving the six or eight chemicals, at no time have we received any scientific data in support of the objection.

Mr. NAUGHTON. But you received the objections.

Dr. HAYS. Just the objections.

Mr. ROSENTHAL. The answer is they didn't withdraw their objections.

Dr. HAYS. No, sir.

Mr. ROSENTHAL. It was in a form unsatisfactory to you?

Dr. HAYS. That's correct.

Mr. NAUGHTON. Were any one of these 252 products to which there were unresolved objections referred to the Secretary of Agriculture as required by the agreement?

Dr. IRVING. No, sir. I believe the record is that we have referred nothing to the Secretary of Agriculture.

Mr. NAUGHTON. So in effect you have not been following the agreement?

Dr. IRVING. We have resolved the issue—we feel we have resolved the issue by taking action.

Mr. NAUGHTON. In other words, you went ahead and put it on the market?

Dr. IRVING. Yes, sir.

Mr. NAUGHTON. Without calling it to the attention of the Secretary of Agriculture as required by the agreement?

Dr. IRVING. The agreement requires if we didn't resolve this that we take it to the Secretary of Agriculture. Our contention is we have resolved it.

Mr. ROSENTHAL. You unilaterally tore up the agreement. That's what you did. Why waste everybody's time? Tell them to take the agreement and forget about it.

Dr. IRVING. I don't want to get into bickering on this either, but I would say, if we said we don't know what to do because of this objection, then we would have reason to send it to the Secretary of Agriculture. We knew what to do, because we registered it.

Mr. ROSENTHAL. How do you get rid of this agreement? Why don't we just get it abrogated somehow?

Dr. IRVING. The agreement is valuable. There are several cases, I think we can cite them, where objections have been raised, supported, and we acceded to those objections.

Mr. ROSENTHAL. Did you think this issue was big enough to bring to the attention of the Secretary? The potential threat of danger or congressional inquiry, either one? [Laughter.]

Dr. IRVING. Lindane pellets?

Mr. ROSENTHAL. And the other products you went ahead and registered in the face of objection. Didn't that sound big enough to take to the Secretary?

Dr. BAYLEY. I might mention here, as one who reviewed this rather recently, that if the Public Health Service had considered it sufficiently serious to provide evidence to the Department of Agriculture that we would have responded differently. As it was, they merely registered an objection without elucidating upon it. Our people could only assume they didn't consider it serious enough to go further.

Mr. ROSENTHAL Did you ever send a letter saying we want your specific objections within 2 weeks or a month?

Dr. BAYLEY. Yes, sir.

Mr. ROSENTHAL. How did they answer that letter?

Dr. BAYLEY. With no evidence whatsoever.

Mr. ROSENTHAL. Your interpretation of this event is that the burden is on them now to show us why they didn't produce more specific information.

Dr. BAYLEY. In accordance with the operation of the agreement, Mr. Rosenthal, every department is to assume their share of this responsibility.

Mr. FOUNTAIN. I wonder if you could give us some examples of some of the objections they raised? Supply it for the record.

(The information supplied appears in the appendix on p. 301.)

Mr. NAUGHTON. Dr. Bayley, is it the responsibility of the Public Health Service to prove that a substance is not safe in order to keep it off the market, or is it the responsibility of those promulgating its registration to establish beyond a reasonable doubt that it is safe?

Dr. BAYLEY. The obligation, of course, is upon the people promoting the registration. On the other hand, if an objection is raised, it can't merely be a statement thereof; in order to deal with the legal aspects of the registration it is necessary that the Department be able to base its decisions on cause and on evidence which is contrary to that provided by the people promulgating the registration.

Mr. ROSENTHAL. Have there been any accidents reported from the 252 products that you registered in the face of HEW objections?

Dr. HAYS. To my knowledge there has not been. I have no absolute proof, but I am of the opinion that the materials we are talking about and the patterns of use, there is no record of any injuries from these uses.

Mr. ROSENTHAL. You are speculating the same way I could speculate. I think you are the man in charge of the statistics——

Dr. ANDERSON. No; I am not in charge of the statistics.

Dr. HAYS. You asked, I think, for an example. We still continue to receive objections for the use of pyrethrum dispensing devices for the dispensing of pyrethrum even though we thought we had fully resolved this question, and after several meetings with the Public

Health Service and agreeing that the continued registration of this product would require on the label, "Do not use in areas where infants, ill or debilitated patients may be confined." We resolved that. But we still continue to get this objection. This is a matter I can't understand.

Mr. FOUNTAIN. Do you find another word to put in place of debilitated?

Dr. HAYS. Aged.

Mr. FOUNTAIN. I was thinking about the label.

Dr. HAYS. We continue to receive objections to some of the mercurials.

Mr. ROSENTHAL. These are objections from the PHS?

Dr. HAYS. That is correct.

Mr. ROSENTHAL. Are you suggesting your relations with them are not good or your communications are not good?

Dr. HAYS. Our communications are fine.

Mr. ROSENTHAL. Or they are sluggish in reacting to your requests?

Dr. HAYS. I think our communications are fine. Our relations are good. It is just a question, I believe, of opinion and judgment as to the use of professional judgment versus scientific data.

Mr. ROSENTHAL. But you had the responsibility when you couldn't reach agreement with them to take it to a higher level. You never did.

Mr. FOUNTAIN. If they don't make the decision themselves.

Mr. ROSENTHAL. But you made the decision.

Dr. IRVING. There was no need to refer it.

Mr. ROSENTHAL. To me that seems outrageous that you did that. Here is a dispute between two Government agencies. You resolve the dispute by unilaterally going ahead and doing what you wanted to do in the first place. Out of gracefulness, why didn't you take it to a higher authority and get the burden off your back? There was no grace in the way you handled this situation.

Dr. IRVING. Let me try once more if I may.

Mr. ROSENTHAL. Do I misunderstand it?

Mr. FOUNTAIN. Maybe you should explain the procedure again, how they bring these objections to your attention. I guess if they get any kind of objection they would bring it to your attention, wouldn't they?

Dr. IRVING. The Secretary of Agriculture is charged with administration of FIFRA, not the Department of Health, Education, and Welfare, or Interior. The Department of Agriculture Secretary has delegated administration of the act to the Agricultural Research Service. We administer in accordance with law and interpretations of the law. That is our practice when a chemical is submitted. The burden of proving this chemical is both safe and effective is on the one who submits the request for registration. Those data are examined by our experts to determine whether, in their opinion, their experience and all their access to the published information on the chemistry, pharmacology, and toxicology of these compounds, that the material submitted is factual, bona fide, accurate evidence of safety and effectiveness.

We then submit for the information and advice of HEW and Interior, this request for registration, and say "What is your reaction to it?"

Mr. ROSENTHAL. Why?

Dr. IRVING. Because the interagency agreement requires we do it.

Mr. ROSENTHAL. It would be a good thing if we didn't have the agreement, wouldn't it?

Dr. IRVING. I think it is an excellent idea. I think it is a fine idea. We submit the request to them. We get their reactions.

In most cases, the vast majority, there are no objections raised by those agencies. In the number we are talking about this morning there have been. The information submitted from HEW and Interior, we have to treat exactly as we do the information from the manufacturer, and the information we get from——

Mr. ROSENTHAL. No, you don't. The manufacturer has an interest in his market being registered. HEW has no profit interest. They are working for the American people.

Dr. IRVING. Yes, sir. I see what you are driving at.

Mr. ROSENTHAL. You are very fortunate you have some pharmacologists and some physicians in HEW who are willing to help you in your responsibility.

Dr. IRVING. Let me pursue that just a little bit further. The material we have to work with from the manufacturer is factual data, experiments on animals.

Mr. ROSENTHAL. It is biased, isn't it?

Dr. IRVING. No, sir. This is factual information, scientific information.

Mr. ROSENTHAL. You don't think he has an interest in your registering his product? I am not saying he is dishonest. He has an interest. HEW has no interest.

Mr. FOUNTAIN. Let him finish going through the process.

Dr. IRVING. This information is scientific information which can stand the test of scrutiny by other scientists and therefore is to that extent factual. There is a natural bias by anybody who is presenting information with the expectation of getting permission to do something. There is that bias. But it is possible with the factual information at hand to remove the bias by consideration of the data, to consider the data on its merits.

When we get an objection from HEW or Interior which is merely a statement to the effect: "We don't like the idea of registering this, period;" then what do we have to consider?

And it is about that category that we are talking now. In the absence of any information, any factual information upon which to base a judgment, we have determined that such objection is not supported and therefore is not valid.

Mr. FOUNTAIN. Who are your experts in your setup who make that determination? And what are their qualifications and background?

Dr. IRVING. Among our experts we have represented all the disciplines that are required to pass judgment on these things—chemists and biochemists, pharmacologists, toxicologists, entomologists, plant specialists.

Mr. ROSENTHAL. In my judgment if one were injured as a result of one of these 252 products you really set the U.S. Government up as a perfect patsy defendant. The U.S. Government, it seems to me, would be absolutely responsible for injuries resulting from the use or misuse or application or injury in any way from any of those 252 products

because in the face of an objection from the Public Health Service, perhaps not in the language you would like it, perhaps not in the specificity you would like it, nonetheless, you arbitrarily, and it seems to me almost arrogantly went ahead and registered the product without complying with the interdepartmental agreement and without trying to protect your own rear forces by a least going to your Secretary and saying, "These fellows are giving us a hard time. Get us off the hook. What should we do?" You just went ahead in complete violation of the agreement.

Mr. FOUNTAIN. Maybe you should submit for the record the language of the agreement so that it will be clear as to just what the responsibility is.

(A copy of the agreement follows:)

INTERDEPARTMENTAL COORDINATION OF ACTIVITIES RELATING TO PESTICIDES BY THE DEPARTMENT OF AGRICULTURE, THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, AND THE DEPARTMENT OF THE INTERIOR

PURPOSE

Coordination of activities of the three departments pertaining to pesticides with special reference to registration and the setting of tolerances to give effect to the pertinent recommendations of the May 15, 1963, report of the President's Science Advisory Committee on "Use of Pesticides."

EXISTING DEPARTMENTAL RESPONSIBILITIES

The following responsibilities of the respective departments relate to the registration of pesticides and the setting of tolerances for pesticide residues:

Department of the Interior

Fish and Wildlife Service.—Conserving beneficial wild birds, mammals, fish, and their food organisms and habitat, with regard to pesticides.

Department of Health, Education, and Welfare

U.S. Public Health Service.—Protecting and improving the health of man in regard to pesticides.

Food and Drug Administration.—Establishing tolerances for pesticides in or on raw agricultural commodities and processed foods.

Department of Agriculture

Agricultural Research Service.—Providing for the safe and effective use of pesticides, including the registration thereof.

AGREEMENT

1. Information

Each department undertakes to keep each of the other departments fully informed of developments in knowledge on this subject from research or other sources which may come into its possession. Additionally, the Department of Agriculture undertakes to furnish to the other two departments on a weekly basis a listing of all proposals affecting registration and reregistration, and the Department of Health, Education, and Welfare undertakes to furnish to the other two departments on a weekly basis a listing of all proposals affecting tolerances. Upon request, the Departments of Agriculture and Health, Education, and Welfare respectively will furnish to the other departments full information about any pending action on registration or the setting of a tolerance.

2. Procedure

(*a*) Each department will designate a scientist to act on behalf of such department in carrying out the terms of this agreement. The weekly listings from the Departments of Agriculture and Health, Education, and Welfare and any additional information relating thereto will be directed to these representatives.

(*b*) The departmental representative will review the weekly listings of actions pending. If there is reason to question any of the items on that list, this

will be communicated to the originating department within one week stating the specific reason for need for further review.

(c) Upon receipt of such request the originating Department will furnish the necessary information and make the necessary arrangements for further review and will withhold final action on the matter for an additional 3 weeks.

(d) If one Department concludes that the proposal should be rejected in whole or in part, this view shall be expressed in writing and shall be supported by appropriate scientific evidence. Upon being notified, the Department responsible for final action will take the initiative to work out a basis for agreement.

(e) In the event agreement is not reached among the Department representatives within 2 weeks of the initial objection, the matter will then be referred directly to the Secretary of the Department responsible for final action with such information, views, and recommendations as the three Department representatives deem appropriate.

(f) The Secretary of the Department charged with final action may then avail himself of whatever administrative and scientific review procedures seem appropriate under the circumstances. The other two Departments will be notified in advance of the proposed final determination of the issues.

(g) The Department representatives will jointly make a quarterly report concerning their activities to the Secretaries of the three Departments.

(h) The departmental representatives are authorized to review questions involving existing patterns of use of pesticides or tolerances upon which they have reason to believe that critical questions exist.

3. Conference

At least once each year the departmental representatives will arrange a general conference to discuss research needs, research program and policy, and the application of research findings in action programs, including public information relating to pesticides.

4. Federal Pest Control Review Board

The Federal Pest Control Review Board may be asked from time to time to consider broad questions on policies relating to pesticides involving the interrelationships of control programs, research, registration, tolerances, and general departmental recommendations to the public.

Dated April 8, 1964.

ORVILLE L. FREEMAN,
Secretary, Department of Agriculture.

Dated March 27, 1964.

STEWART L. UDALL,
Secretary, Department of the Interior.

Dated April 3, 1964.

ANTHONY J. CELEBREZZE,
Secretary, Department of Health, Education, and Welfare.

Mr. ROSENTHAL. Do you have any medical doctors, physicians on your staff that review these pesticide registrations?

Dr. IRVING. On the staff? No, sir. We have three consultants who are M.D.'s whom we call in for advice on such matters when we feel this advice is needed.

Mr. ROSENTHAL. Do you have written reports from any of them on the 252 products?

Dr. HAYS. No, sir.

Mr. ROSENTHAL. None at all?

Dr. HAYS. On lindane, yes.

Mr. ROSENTHAL. Lindane was the one product you continued for 18 years and you only recently took it off?

Dr. HAYS. That is right.

Mr. ROSENTHAL. Your track record is not good.

Dr. BAYLEY. Mr. Rosenthal, ARS, in making such a decision recognizes fully that they are accountable before the courts if necessary to produce the evidence on which they refused a registration.

Now, without such evidence they don't feel they can responsibly react to this kind of decision.

Mr. ROSENTHAL. Do you think such evidence might be a statement from the Public Health Service?

Dr. BAYLEY. Such evidence could be provided if they have it.

Mr. ROSENTHAL. In my judgment, as a lawyer, that would be pretty convincing evidence.

Dr. BAYLEY. If they would provide it. If there is evidence. It can't merely be an opinion.

Mr. ROSENTHAL. You mean to say that the matter to this date is unresolved? That you implore Public Health Service to please give us more specific evidence and they continue to refuse to do that?

Dr. BAYLEY. In the case of lindane we finally produced the evidence ourselves.

Mr. ROSENTHAL. Is that true?

Dr. IRVING. That's right.

Mr. FOUNTAIN. They didn't have it available?

Mr. ROSENTHAL. They arbitrarily refused to give it to you?

Dr. BAYLEY. We produced it ourselves.

Mr. NAUGHTON. Who was right? You or PHS?

Dr. BAYLEY. They were.

Mr. NAUGHTON. Is that the only product you tested yourself for 18 years?

Dr. BAYLEY. You see, in order for three agency agreements to work, all three agencies have to carry their share of this. This is the important thing.

Mr. ROSENTHAL. All I am saying is why not go to the Secretary and say, "Look what these fellows are doing to us? Will you straighten it out at your level?" You are straightening it out at your level.

Mr. NAUGHTON. If you tested one product they objected to and they were right, their batting average is a thousand.

Dr. BAYLEY. On one incident. Let's not go to percentages on one incident.

Mr. NAUGHTON. We are talking about human beings here. Before the Senate, in response to a question of Senator Hart, you indicated if two pesticides were equally effective and one had bad side effects, was more dangerous than the other, that you would cancel the one that had the bad side effects.

Now, in terms of any of these products to which PHS or some other agency raised an objection, was any attempt made to determine whether or not there was an equally effective product available to which PHS had no objections?

Dr. BAYLEY. As I understand it, within the law and within the interpretation of what I said to Senator Hart, it is a matter of a product being safe or not safe. Only in this case would there be an alternative.

Sometimes our understanding of the hazards of these products are changeable at times.

Mr. NAUGHTON. Then you don't make any attempt to measure whether there is a safer product which is equally effective?

Dr. BAYLEY. It is my understanding we are obliged to register a product if it is established as safe within the recommended use.

Mr. FOUNTAIN. Do you feel ARS has adequately considered the ob-

jections made by the Public Health Service to the products which have been proposed for registration? Any of you?

Dr. IRVING. Yes, sir; I do.

Mr. FOUNTAIN. Can anyone in the Agricultural Research Service provide the subcommittee with an accurate figure at this time as to the total number of products being marketed to which PHS has objected?

Dr. HAYS. Yes.

Mr. FOUNTAIN. You can supply that?

Dr. HAYS. Yes.

Mr. FOUNTAIN. Do you have the information now?

Dr. HAYS. We don't think we have it all, sir.

(The following statement was subsequently provided:)

To obtain accurate figures as to the number of products which are being marketed to which Public Health Service objected would necessitate an extensive review of records. We will be pleased to furnish these figures if it is still the desire of the committee.

Mr. FOUNTAIN. Committee stands recessed for 10 minutes so that Members can respond to a quorum call and then we will return.

(Recess.)

Mr. FOUNTAIN. The committee will come to order. Let the record show a quorum is present at the resumption of the hearing.

Whenever I call one of you by name, I am not presuming you are the one best prepared to answer the question, so don't hesitate to call the one particularly equipped to do so, or feel free to supplement one another.

We want an accurate record.

At this point, while we are on the subject of objections by other agencies, I would like to ask this question:

I think you are in enough trouble from the standpoint of what you haven't done, but I would like the record to be completely clear. Does the Public Health Service make the kind of check that you make on these pesticides?

Dr. IRVING. They can have access to the same information we have.

Mr. FOUNTAIN. Do they get that information without getting it from you?

Dr. IRVING. No.

Dr. HAYS. We don't submit——

Mr. FOUNTAIN. What information do they have available to them when they submit an objection to you, to the registration of a particular pesticide?

Dr. HAYS. They ask for the data which has been submitted. This is supplied to them, along with the labels which are transmitted daily, on the review of pesticides.

Mr. FOUNTAIN. So you do submit to them the same information that you have?

Dr. HAYS. In general, yes.

Mr. FOUNTAIN. Do you submit all the information you have on the pesticide?

Dr. HAYS. No. Only upon request.

Mr. FOUNTAIN. Do they request it often?

Dr. HAYS. Very often.

Mr. FOUNTAIN. Do they raise objections without examining the material which you have?

Dr. HAYS. I would assume in some of these they have probably not requested all the data over the years, but have objected on their professional judgment.

Mr. FOUNTAIN. Has PHS ever volunteered information to you about pesticides?

Dr. HAYS. Not routinely. I wouldn't say they hadn't.

Mr. FOUNTAIN. In other words, there is no understanding or sense of responsibility between the two agencies to supply the other with information except upon request.

Dr. HAYS. That's correct.

Mr. FOUNTAIN. Getting back to specifics, I believe the last question I asked was whether or not you felt that ARS had adequately considered objections made by the Public Health Service to products proposed for registration. You said you thought you had, or were doing it.

Then I asked you to provide us with a figure as to the total number of products being marketed to which PHS objected, and I believe you said you would supply that for the record.

Dr. IRVING. Yes, sir.

Mr. FOUNTAIN. Would it be true to say, then, that no one knows how many such products are on the market because you don't keep records showing this information? Would it be necessary to search individual files for all registered products to obtain this information?

Dr. HAYS. That's correct.

Mr. FOUNTAIN. Had it ever occurred to you that it might be a good idea in situations where ARS has disregarded objections by PHS and allowed a product to be marketed to keep a particularly close watch on those products?

Dr. HAYS. I think we are fully aware of this, and have advised our people to be particularly concerned about these products.

I would like to remind you that many of these objections are for products that have been registered for many years, and I think here its even more important in requesting that we refuse registration, that we do have the kind of data necessary to form a basis for justifying this objection.

Now, it seems to me that if it is so obvious to the Public Health Service personnel, surely there must be some good basic reason for the objection. There must be data available to support that objection.

Mr. FOUNTAIN. Has ARS customarily advised the Public Health Service of the disposition of their objections and suggestions on product registrations?

Dr. HAYS. Not routinely.

Mr. FOUNTAIN. You haven't felt that it was desirable or necessary?

Dr. HAYS. In several instances where it involved a large number of compounds, I advised the Assistant Surgeon General about late 1966, of our position regarding the objections and of the actions we were going to take in this regard.

Mr. FOUNTAIN. Have they ever come back after they discovered you had made your decision notwithstanding their objections, and objected again on any product?

Dr. HAYS. In this particular category that is true. They have not come back except to continue the same remark, that they object. In one particular group involving some mercury compounds, I discussed this matter with the Assistant Surgeon General, and with his concur-

rence, we agreed that we would not register any new mercury compounds. We would continue to register those that had been previously registered.

I recommended that the Public Health Service engage in an epidemiological study, because it seemed to me, as a toxicologist, that it was rather fruitless to continue to do animal experimentation on products of this type when the literature is full of this kind of data.

What we needed so desperately was an epidemiological study. I requested this of the Public Health Service. We have not received any such report of this type of study that I think is essential.

Mr. FOUNTAIN. I wonder if you would explain to us how you operate in terms of mechanics. You get an objection from the PHS, for instance; is that in writing?

Dr. HAYS. Yes.

Mr. FOUNTAIN. After you examine that objection do you have occasion to have a personal conference with somebody from that agency to discuss the pros and cons of the objection, or do you just write back and tell them what you think, or just don't write back at all, but go ahead and make your decision?

Dr. HAYS. We have numerous ways of communicating. By phone, personal conversations and by letter. Usually it's a conversation by phone, trying to explain the reason for our continued registration.

Mr. FOUNTAIN. Have they ever withdrawn any objections on any products?

Dr. HAYS. Yes.

Mr. FOUNTAIN. Is that after consultation and discussion?

Dr. HAYS. Yes.

Mr. NAUGHTON. Dr. Hays, you indicated that the Public Health Service hadn't given you the epidemiological studies you requested on mercury compounds from PHS.

Its not up to PHS to prove a compound is unsafe, is it? Isn't it up to the manufacturer to prove its safe before it can be marketed?

Dr. HAYS. I think we are all concerned with the registration of pesticides, their safety, and effectiveness.

Mr. NAUGHTON. Isn't it the responsibility of the manufacturer to prove a compound is safe and effective?

Dr. HAYS. I don't know that it would be the responsibility of the industry to carry out an epidemiological study. I recommended to the Surgeon General—this is an area in which they have great expertise. I know of no agency better qualified to do an epidemiological study.

Mr. NAUGHTON. You are no longer registering new ones, are you?

Dr. HAYS. It was agreed not to register any new ones. This, in our opinion, seemed a reasonable solution to our problem. What we were concerned with was the continued registration of those things which they had concern about, and offered objections to.

Mr. NAUGHTON. What is reasonable about a solution which prevents new registration of a particular product, but permits those who had prior registrations to continue to flood the market with unlimited quantities of the same substance for which you have a concern about safety?

Dr. HAYS. Those things have been on the market for many years. We had no reason to question their registration, for we had no reports of any adverse effects from the uses of patterns of use for these particular compounds.

Mr. NAUGHTON. If you think they are safe enough to stay on the market, why don't you let the new ones on?

Dr. HAYS. These are new compounds on which we don't have the years of experience we have with the old ones.

Mr. NAUGHTON. You don't have sufficiently adequate accident reports to know the number of accidents that resulted from those on the market, do you?

Dr. HAYS. Not accurate and complete, no.

Mr. FOUNTAIN. Dr. Hays, at our last hearing you were asked whether ARS had ever received an objection from PHS to the chemical used in Shell's "No-Pest Strip," and you responded, "Not to my knowledge."

Isn't it true that PHS actually objected on a number of occasions, beginning with the first time of registration of the No-Pest Strip?

Dr. HAYS. I'm not aware of any specific objections. There may well have been.

Mr. FOUNTAIN. Do you have any information on that?

Mr. NAUGHTON. My understanding is they did object.

Mr. FOUNTAIN. Do you have documentation?

Mr. NAUGHTON. Mr. Myers?

Mr. MYERS. Yes.

Mr. NAUGHTON. We can put the documentation of the objections in the record.

(NOTE.—Documentation of PHS objections to registration of Shell's "No-Pest Strip" is contained in a letter from HEW to the subcommittee. Pertinent excerpts from the letter were subsequently read into the record by Congressman Rosenthal.)

Mr. FOUNTAIN. It is true that the objection was withdrawn as a form of compromise in return for a warning on the label that the No-Pest Strip should not be used in rooms where infants or infirm people are confined?

Dr. HAYS. I don't know if that was a compromise. Following our actions on the continuous dispensing of pyrethrum and the statement, "Don't use where infants and aged persons may be confined," the next question was a similar statement for vapona, and we agreed. This statement does now appear on these packaged units.

Mr. FOUNTAIN. But you are not aware of a meeting of the minds on the label or the objection?

Dr. HAYS. We agreed that the statement should be on the label.

Mr. FOUNTAIN. You are not aware of any agreement with PHS?

Dr. HAYS. I am not aware of compromises.

Mr. FOUNTAIN. Is anyone here familiar with that? Anyone who can give details concerning the compromise or how it came about?

Would you supply that for the record, if you can get the information?

Dr. HAYS. Yes.

(The following material was subsequently provided:)

According to our records there was no compromise. On July 28, 1966, the Public Health Service objected to the registration of Shell's product. They stated that "We do not recommend the registration of this registered number because the devices used deliberately subject human beings to continued exposure to a pesticide. Furthermore, this type of device is nondiscriminatory in that it subjects both humans and insects to the same concentration of pesticide. This is verified in Dr. R. J. Anderson's letter to you of June 4, 1965."

At this time, we registered the product based on Dr. Anderson's letter dated October 13, 1965 to Dr. R. W. Weiger, in which it was stated that registration could not be withheld since the Public Health Service had no scientific evidence to support their objection. Section 2(d) of the interagency agreement states "If one department concludes that the proposal should be rejected in whole or in part, this view shall be expressed in writing and shall be supported by appropriate scientific evidence."

In 1967 the Public Health Service agreed, in discussions with the Shell Chemical Co., that they would not object to registration of this product if the statement, "Do not use in rooms continuously occupied by infants or infirmed individuals" was added to the label. Pesticide Regulations Division notified the Shell Chemical Co. that this statement would be required.

On April 3, 1969, Public Health Service again reviewed the label for Shell's vapona and had no adverse comment.

Mr. FOUNTAIN. Was anyone in Shell involved in any way in the negotiation or background work leading to—you say you are not familiar with the compromises—leading to the decision to put that on the label, that warning?

Dr. HAYS. The Shell Co. was advised that this statement would have to appear on the labels.

Mr. FOUNTAIN. As I understand it, the registration for Shell's No-Pest Strips has been changed now so that a statement warning against use in rooms where infants and infirm people are confined is required.

Dr. HAYS. That's correct.

Mr. FOUNTAIN. I am just trying to straighten out some of your statements. At our last hearing, as I recall, you were asked whether any actions had been taken to require relabeling of No-Pest Strips already on the market to include the warning against exposure and I'm told that your response was that you didn't see any particular need for such action.

Was that an indication that you didn't know about the relabeling or didn't agree with the decision made?

Dr. HAYS. No. I think, Mr. Chairman, as I remember that statement, I reported to you that we did require this statement to appear on the product, on the label.

I didn't see any reason to require recall of all the products that were on the market at that time, to place the same statement on those labels.

Mr. NAUGHTON. I might read that excerpt from the testimony. This is from the transcript of our hearing of May 7:

Mr. NAUGHTON. Have you taken any action to require relabeling of products now on the market?

Dr. HAYS. No, we don't see any particular need for recalling these.

Now, do you see any need for relabeling products on the market, and have you taken action to do so?

Dr. HAYS. Mr. Naughton, from the use experience it would not seem reasonable to require these packages, wherever they may be, to have this statement. We think that this is a proper statement for any new material being shipped into the channels of trade.

It is our effort, day after day, based on any new evidence that we have, to upgrade our labeling, but in many instances it would not be deemed reasonable to require it on the material that is in the channel of trade.

Mr. NAUGHTON. Doesn't the present registration of Shell's No-Pest Strip require that it carry the warning for infants and infirm people?

Dr. HAYS. That's right.

Mr. NAUGHTON. Then isn't any of this product now being shipped or held for sale in interstate commerce without that warning on the label misbranded under the act which you are to enforce?

Dr. HAYS. I would not judge it so.

Mr. NAUGHTON. Let me ask the legal expert, Mr. Bucy, what is your judgment on that?

Mr. BUCY. If a registration requires certain warnings, then a product that is being held after its movement in interstate commerce for sale in its original package, the label of which does not conform with the registration in this regard, would be subject to possible seizure action.

Mr. NAUGHTON. If it doesn't bear the warning, it can be seized and taken off the market.

I can tell you that you can look in many stores in the Washington area and find large stocks of Shell No-Pest Strip which don't bear that warning. Is it your position that, even though this may be a violation of the law, you don't see any need to enforce the law in this case?

Dr. HAYS. That isn't the question it seems to me, of enforcing the law. We tried to do what we thought was reasonable and practical, Mr. Naughton.

Mr. NAUGHTON. Excuse me. I missed that.

Dr. HAYS. I said it would seem to me we were trying to do what is reasonable and practical. It isn't a question of necessarily enforcing the law.

Mr. NAUGHTON. It is not a question of enforcing the law as far as you are concerned as Director of the Pesticides Regulation Division. It is a matter of doing what you think is reasonable and practical and let the law go?

Dr. HAYS. I didn't say that.

Mr. ROSENTHAL. No other interpretation is possible. Mr. Bucy said it is a violation of law. You said in your judgment it is not reasonable. You and I have no right to make judgment when the law is on the books and counsel interprets it that way.

Mr. NAUGHTON. Who made the decision, if a formal decision was made, that there was to be no seizure action with respect to Shell's No-Pest Strip or that no action was to be taken to require Shell to send someone out to stamp on the face of each of these packages the warning that the registration requires it to bear?

Dr. HAYS. It wasn't necessarily an action. It was simply a question that we have not taken any—

Mr. NAUGHTON. And you have no intention of taking action, do you, if you are left to your own desires?

Dr. HAYS. I didn't mean to imply we would not take action. I simply said it didn't appear to me to be practical in this instance. That does not mean we would not take action if it was deemed necessary.

Mr. NAUGHTON. What was impractical about it? Shell is a big company. They could find somebody with a rubber stamp to go around and put the warning on the packages.

Mr. FOUNTAIN. Do you have any information indicating how much of it is already on the market before the label——

Dr. HAYS. No, I don't.

Mr. NAUGHTON. Was any inquiry made of the company as to how much——

Dr. HAYS. No, sir.

Mr. NAUGHTON. What was the information upon which you made the decision that the label should have that warning, that it shouldn't be used in rooms where infants on infirm people are confined?

Dr. HAYS. The pharmacology of this particular compound is such that if one is exposed excessively to the material, it is conceivable that it could bring about some physiological response. I believe all of those involved in this matter would agree that it is not in the best interest of good medicine to permit a geriatric patient who may have some bronchial difficulties, such as emphysema, to be exposed to a material that might adversely affect the individual.

Now, we don't have any concrete evidence of this, but that is a matter of good medical practice. It is conceivable that infants may also have some pulmonary diseases that only would make the matter worse by having them continuously exposed.

Therefore, it seemed to me, and the Public Health Service, good medical practice to not permit these on a continuous basis.

Mr. NAUGHTON. So, notwithstanding that decision with respect to the new labels, you didn't feel that it would be reasonable or practical to insist upon a recall or a change of the labels on merchandise already in the market.

Dr. HAYS. Again, Mr. Chairman, this is prophylactic, and we hope preventive, but it certainly was not based on any actual cases of reported accidents.

As a matter of fact, there have been some studies carried out in one of the foreign countries by a very capable physician in which these have been placed in hospitals and areas where infants are confined. And there is some doubt that any adverse effects would be produced, but even then it seems to me good medical practice not to condone it.

Mr. NAUGHTON. At our last hearing on May 7, Doctor, you indicated that no action had been taken to publicize the fact that there was now a warning notice required to be distributed in connection with Shell's No-Pest Strip. In other words, even though many people undoubtedly have boxes of No-Pest Strip in their home that were bought previously which don't bear the warning and have no idea that this caution is now required to be on the label, you indicated at that time you had taken no action to publicize this warning.

Have you taken any action since the hearing?

Dr. HAYS. We have made no public announcements in this regard. But I think it may well be, Mr. Naughton, that this is a very good approach to use every medium possible to alert the public to anything that has brought about a change which they should be aware of.

Mr. NAUGHTON. Would you go further to agree it might be a good thing to issue a specific warning notice to warn the public in every instance where you encounter a situation where a product on the market may be dangerous to health or have other adverse results?

Dr. HAYS. I think this has virtue.

Mr. NAUGHTON. I have here a press release of May 22, 1969, issued by the Agricultural Research Service. This is the Veterinary Biologics Division. They had a situation in which some cattle came down with blackleg shortly after being vaccinated. There was concern that the disease might have been caused by the bacterin. We might put in the record a warning notice that was issued by the Agricultural Research

Service's Veterinary Biologics Division—I understand this is probably their standard procedure—to warn owners of cattle against the possibility of harm to cattle from a registered product or approved product that was on the market.

(The press release follows:)

TWO SERIALS OF BLACKLEG-MALIGNANT EDEMA BACTERINS UNDER QUESTION

The U.S. Department of Agriculture notified livestockmen today that the safety of two serials of blackleg and malignant edema bacterin is under question.

As a result, Dr. John M. Hejl, Director of the Veterinary Biologics Division of USDA's Agricultural Research Service, urges cattlemen and veterinarians not to use bacterin doses in the two serials numbered 67163 and 67165. About 360,000 doses of each serial were produced and distributed throughout the United States by Chas. Pfizer & Co., Inc. The manufacturer has issued a notice of recall for the serials. Their shelf life normally would extend through January 1971.

USDA states that the manufacturer complied with Federal regulations affecting the combination bacterin in question, and it passed all company tests for safety, as well as efficacy and purity. Confirmatory tests for the two serials by USDA also were satisfactory, and only then were the serials released for marketing in July 1968.

No problems arose until two cattle out of 149 on a California feedlot came down with suspected blackleg after they had been vaccinated with one of the two serials. (It is not known which of the two serials was involved.)

The California State Livestock and Poultry Pathology Laboratory at San Gabriel reported testing doses of the bacterin left from material used at the feedlot that had the trouble, and isolation tests showed live pathogenic bacteria in the two serials in question.

ARS Veterinary Biologics Division has not had sufficient time to recheck the two serials. Withdrawal of the serials from the market at this time is a precautionary measure, begun with the full cooperation of the manufacturer.

The suspect combination blackleg and malignant edema bacterin, technically called Clostridium Chauvoei-Septicum Bacterin, with the serial number 67163 or 67165, should be returned to the supplier from whom the bacterin was purchased.

Blackleg and malignant edema are infectious bacterial diseases of cattle highly fatal to calves 6 to 18 months old. Bacterin against these two diseases contains killed bacteria that help cattle produce antibodies against possible later invasions of the same bacteria. Bacterins that pass quality control tests usually are safe.

Mr. NAUGHTON. It speaks for itself, but would it be possible to get equal treatment for humans?

Mr. ROSENTHAL. We went through that last week. Congressman Neal Smith told us of how the value in terms of hogs—you tell them what percentage of protein and what the contents are, but humans can't get it.

Smith suggested to us that, because hogs and cattle are property, they have a special high priority in our society. That may be true.

As an amendment to Mr. Naughton's recommendation, what about putting up in post offices the 10 most dangerous pesticides right alongside the other list?

I wanted to ask a question. This warning on Shell. Was that something PHS suggested you do?

Dr. HAYS. I think it was with a meeting with representatives of the PHS and Agriculture that it was agreed this was desirable to do.

Mr. ROSENTHAL. Was it on their initiative?

Dr. HAYS. I don't recall if it was. I do remember discussing this with representatives of the Public Health. Who originated it, I can't say.

Mr. NAUGHTON. They objected to the sale, and as I understand it, they withdrew their objections to it being on the market at all as a——

Mr. ROSENTHAL. They apparently compromised with this warning on; isn't that the case?

Mr. FOUNTAIN. I asked him earlier and he said he was not mindful it was a compromise or that they objected, but they did confer.

Mr. ROSENTHAL. They filed an objection.

Mr. NAUGHTON. You spoke of a meeting. Were you at the meeting?

Dr. HAYS. Yes.

Mr. NAUGHTON. Were there representatives of Shell present?

Dr. HAYS. No, sir.

Mr. NAUGHTON. We discussed in some detail the action, or perhaps we should call it more accurately lack of action, with respect to Shell's No-Pest Strip. Is there another product which in some respects at least is similar to Shell's No-Pest Strip? As a matter of fact, that contains the same active ingredient in the same proportions, I understand, which was formerly on the market and which has been taken off the market by action of the Pesticide Regulation Division? I am speaking of a product manufactured by the Aeroseal Co.?

Dr. HAYS. Yes.

Mr. NAUGHTON. Would you describe that situation for us or have whoever is familiar with it give us a little chronology and indicate why you took that product off the market while not even causing a warning notice to be put on the boxes of Shell's product?

Dr. HAYS. Mr. Naughton, as I recall, this product was marketed some years ago as a vapona strip and supplied, I believe, by the Shell Co., marketed by Aeroseal.

Mr. NAUGHTON. In other words, they bought the material from Shell and marketed it in their own packages?

Dr. HAYS. I presume that is correct. It was registered, and then for some reason the Aeroseal people no longer marketed this product, but marketed and manufactured their own product.

Mr. NAUGHTON. In other words, they stopped buying their supplies of vapona from Shell and produced their own vapona?

Dr. HAYS. That is correct.

Mr. NAUGHTON. Was it the same chemical?

Dr. HAYS. That is correct.

Mr. NAUGHTON. No difference?

Dr. HAYS. That is right. Now, we had an occasion to sample this product and found that it was something entirely different than any resin material that had previously been reviewed.

In fact, it wasn't even a resin. It was simply a piece of blotter paper in which the vapona had been inpregnated in the blotter paper, and it was wrapped with a little Saran wrap. And when I looked at it, it was obvious that this was not a well-marketed product in which they would incorporate the vapona into a material that was designed to release it at a constant rate. So, this product didn't then comply with the registration requirements. It hadn't been submitted for registration. No data had been submitted as to the effectiveness. No data had been submitted as to the rate of dissipation. No data had been submitted as to safety. So, we saw no resemblance, and not being registered in this form, we took action to cancel.

Mr. NAUGHTON. How did you happen to take a sample of the Aeroseal product?

Dr. HAYS. Now, that I am not completely familiar with.

Mr. NAUGHTON. Was it on a complaint from Shell?

Dr. HAYS. It could well be.

Mr. NAUGHTON. The Aeroseal people stopped buying their supplies from Shell and began manufacturing their own. Was there any difference you know of in the active ingredient? There was none, you said. Am I correct that the basic difference between the Aeroseal vapona strip and Shell vapona was impregnated while Shell used a resin substance.

The amount of vapona in each case is approximately the same, is that right?

Dr. HAYS. Yes.

Mr. NAUGHTON. Both of the strips have the same recommended directions for use, do they?

Dr. HAYS. I presume they did.

Mr. NAUGHTON. They are to be hung up in a room and the vapors will fill the room. The Shell strip advertises it will last for 3 months. Do the Aeroseal people make the same claim?

Dr. HAYS. I am sure they had a period of time on it.

Mr. NAUGHTON. Now, how long did it take you to get Aeroseal off the market after the complaint from Shell came in?

Dr. HAYS. Well, it must have been at least several weeks after we had received the sample and had tested or inspected it. I couldn't give you the dates. I can provide those for you.

Mr. NAUGHTON. How long did it take you to demand they take it off the market?

Dr. HAYS. Once we issued the notice to the registrant that the product was canceled, it took only a matter of a few days to ask the company to recall this product on the basis that we had no information regarding its properties.

Mr. NAUGHTON. Is it correct—I am not certain when the complaint from Shell came in, but is it correct that the sample was taken on March 20, 1969, and that on March 24, 1969, 4 days later, you demanded that the product be taken off the market? I don't want anything I say to be interpreted as indicating I think it should still be on the market. I am just comparing the treatment of Aeroseal with Shell No-Pest Strip.

Dr. HAYS. I would say that was a very effective and proper move, done very expeditiously.

Mr. NAUGHTON. Is this the fastest track record you ever had for getting a product off the market?

Dr. HAYS. I wouldn't be able to answer that.

Mr. FOUNTAIN. How long was it?

Mr. NAUGHTON. Four days to demand it be removed. It perhaps took a little longer before it was actually off.

Mr. ROSENTHAL. That action was initiated because of a complaint by Shell?

Dr. HAYS. It wasn't initiated by a complaint. We receive a complaint from people across this great country.

Mr. ROSENTHAL. Did you get complaints from the PHS on that product?

Dr. HAYS. I don't know that PHS was aware of this particular product at that time.

Mr. NAUGHTON. The information we have is that the reason the sample was taken was because of a complaint by Shell. Is there anybody here who could clear up the discrepancy? Was it or was it not a complaint from Shell that led to the taking of the sample?

Dr. HAYS. It was not the complaint by Shell. No action was taken until we had a sample of this product and found, No. 1, it was not registered.

No. 2, it didn't have any performance data. Three, there was no safety data. And, four, it was not in the form in which it had been presented to us as being a bona fide product by that company. It bore no relationship to the Shell Co.

(The following additional statement was subsequently provided:)

The Shell Chemical Co. informed the Pesticides Regulation Division that a product was being marketed by Aeroseal Co. under their trade name although Shell no longer supplied this material to Aeroseal. We requested our inspector to sample the Aeroseal product and upon receipt found that it bore no resemblance to the product that Aeroseal had previously registered with the Division. On the basis of the fact that this product was not registered and that we had no information as to its performance it was decided that the product should be immediately recalled. The sample was collected on March 20, 1969, and the suspension was issued on March 24, 1969.

Mr. ROSENTHAL. Mr. Chairman, may I go back a little? I did ask Dr. Hays earlier whether or not it was a Public Health Service or Agriculture that had stimulated the warning on the Shell product and he didn't recall.

I would like to read into the record at this point a letter from the Department of Health, Education, and Welfare, addressed to this committee that says as follows:

The initial discussions with representatives of both the Shell Chemical Co. and the Pesticide Regulations Division of the U.S. Department of Agriculture were held at Atlanta by Dr. S. W. Simmons and Dr. Wayland J. Hayes. During these discussions Dr. Simmons informed both groups that we would withdraw our objection to registration provided the label bore the statement. "Do not use in rooms continuously occupied by infants or infirm individuals." Following these discussions Dr. Simmons sent Dr. Harry W. Hays a copy of the enclosed letter to Representative Sullivan, dated September 28, 1967....

The letter goes on to say:

Labels continued to be referred to us without this additional cautionary statement and in each weekly letter we forwarded the same comment that appeared in our letter of December 15, 1967. The dates of our letters in which this comment appeared were: January 5, January 19, April 5, May 10, July 26, October 4, December 6, 1968, and February 7, 1969. After February 9, 1969, we discontinued our objection because the labels bore the suggested statement.

Doctor, does that refresh your recollection as to who initiated the warning statement?

Dr. HAYS. It must have been the Public Health Service.

Mr. ROSENTHAL. It strikes me as unique, this comparison between the 4 days that it took to get this other one off the market and the seven or eight letters and communications from the PHS before you ever even agreed to this warning label on the Shell product. It seems strange.

Dr. HAYS. I can't explain the dates and delays in this matter. I can only say we heartily agreed with Dr. Simmons, with this idea. I think it was a very excellent recommendation. The delay in making the change is something I can't explain at this moment.

Mr. NAUGHTON. Perhaps it might expedite matters if I asked Mr. Alford, Assistant Director, Registration, to tell us a little more about the Aeroseal situation and the timetable involved there.

Mr. ALFORD. Yes, sir.

Mr. NAUGHTON. You are Harold G. Alford, Assistant Director for Registration, Pesticides Regulation Division. How did you happen to have a sample taken of Aeroseal?

Mr. ALFORD. Representatives of the Shell Co., did bring a sample of the product they had collected to the office and did, in fact, file a complaint about it. This is not unusual for one industry to do that about another.

On the basis of such complaints, we routinely asked our enforcement people to collect an official sample so that we may determine for ourselves what the status is. This is done quite frequently.

Mr. NAUGHTON. Normally the procedure is to have a sample taken and then have a lab analysis made and then take action based on the lab analysis?

Mr. ALFORD. If the analysis is required to determine whether or not it is in compliance with the act; yes.

Mr. NAUGHTON. Are those dates correct that I gave? March 20, 1969——

Mr. ALFORD. It was within a few days from the time the sample was collected before we did send out the letter.

Mr. NAUGHTON. Did you have a report from the lab as to the analysis of the sample at the time the letter was sent out?

Mr. ALFORD. No.

Mr. NAUGHTON. Had you received any reports of accidents due to Aeroseal prior to taking action to remove it from the market?

Mr. ALFORD. I don't think so.

Mr. NAUGHTON. Now, it is my understanding that normally a cancellation of a registration takes perhaps 15 months. It is a rather involved procedure. How were you able to initiate the action in such a short period?

Mr. ALFORD. Upon examination of the product, the official sample that was collected, it was obvious we had no data on the release rate, on what the potential hazard of the product would be. It was determined that such a use would be potentially hazardous and it was decided that it should be suspended to prevent a hazard to the public.

Dr. IRVING. I think the answer to the question is that this was not a registered product. Aeroseal was not a registered product.

Mr. NAUGHTON. Didn't you suspend the registration?

Mr. ALFORD. The product being marketed was not the product represented in connection with registration.

Mr. NAUGHTON. What authority do you have to suspend a registration without going through cancellation——

Mr. ALFORD. To prevent an imminent hazard to the public.

Mr. NAUGHTON. Is that the basis on which you took action?

Mr. ALFORD. Yes.

Mr. NAUGHTON. What was the nature of the imminent hazard you had in mind?

Mr. ALFORD. It was the best judgment of Dr. Hays and the other people in the evaluation that this was a potential hazard to the public, and in order to prevent an imminent hazard, suspension of registration was warranted.

Mr. BUCY. I think the record should be made straight on this. I think the gentleman is possibly misspeaking himself because the product that we are talking about was not the product that was registered. Therefore, it was a matter of telling the party that you have a nonregistered product here and therefore we could recall it. It is subject to seizure. That is what I understood was it——

Mr. NAUGHTON. Were you consulted in advance of this action?

Mr. BUCY. I am sure that my office was talked to. I think one of my men reported to me that they had a nonregistered product here and the answer is if it is nonregistered it is subject to seizure and either the most effective way of getting it all off is to get the party to recall their product wherever it may be.

Mr. NAUGHTON. Without disagreeing with your interpretation of the law in any way, let me again confirm what happened. Mr. Alford, you were acting under the impression you were taking this off the market because it was an imminent hazard?

Mr. ALFORD. Because it could have been. Also, it was not the product represented.

Mr. NAUGHTON. But the imminent hazard was part of the basis on which you thought you were proceeding.

Mr. ALFORD. For the immediate action.

Mr. COPENHAVER. By the same logic as this gentleman here presented, the Shell product was not the product registered because according to section 3A1 of the Pesticide Act it is prohibited to market any product, any economic poison if any of the claims made for it or any of the directions for its use differ in substance from the representations made. Since the Shell product failed to have the proper warning on it it was different from the representations made in the registration and the same logic should also have been used there.

Mr. BUCY. That is what I stated in answer to Mr. Naughton's question.

Mr. ROSENTHAL. As I understand counsel's position it was a different product once it didn't bear the label and it should have been seized.

Mr. BUCY. It may be the same product, mislabeled.

Mr. COPENHAVER. Is the gentleman questioning my interpretation of the law?

Mr. BUCY. No. I am stating mine.

Mr. FOUNTAIN. He said he concurred with you.

Mr. COPENHAVER. But the action taken against the Shell product was different than the action taken against the Aeroseal product.

Mr. ROSENTHAL. That appears to be the case.

Mr. COPENHAVER. Under the same philosophy.

Mr. NAUGHTON. How many times, in the memory of any of you gentlemen here, prior to the Aeroseal situation, when imminent hazard was at least a part of the motivating process, have registrations been suspended on the ground of imminent hazard? Do you know any other cases in which this has happened in the 20-year history of the act?

Mr. ALFORD. We possibly had some in the past. I am not familiar.

Mr. NAUGHTON. Nobody knows of another one at this time. I won't ask for this to be submitted to the record.

Mr. FOUNTAIN. Was someone about to answer the question?

Mr. ALFORD. Mr. Miller suggested one previous case we had where registration was suspended.

Mr. NAUGHTON. Could anyone enlighten us, in view of the similarity of the products, the Shell No-Pest Strip and Aeroseal Vapona Strip which had exactly the same active ingredients and practically the same, if not identical, directions for use, what made one an imminent hazard when the other didn't give you enough concern that you even thought about having the warning put on the boxes in the stores?

Mr. ROSENTHAL. After six letters from the PHS.

Dr. HAYS. It bore no similarity to the resin strip that Aeroseal previously marketed that was the vapona strip of Shell. They, on their own volition, decided to make their own strip. When I looked at it, it bore no similarity to the Shell strip, and to me, it did pose a very serious threat in that the material was taken up in a blotter.

I don't want to get into the physical chemistry of the problem involved, but it is inconceivable to me that this material could be released at a very constant rate when all it was bound to was a piece of blotter paper. That, to me, is dangerous, and unless we had evidence to the contrary, under certain conditions of temperature and humidity, the amount of material could be released very rapidly and the amount in the atmosphere could reach a level that could produce some very serious effects.

I didn't think that was adequate protection to the public, to allow this product to be on the market without any data to support it.

Mr. ROSENTHAL. Mr. Bucy just said the reason for the seizure was something else.

Mr. BUCY. I said the product was not registered. It was a product other than the registered product. Therefore, it wasn't a matter of having to suspend or revoke a registration, because it was a nonregistered product.

Mr. COPENHAVER. My point was the Shell product is also a nonregistered product under the law.

Mr. NAUGHTON. Doctor, you indicated there was no similarity between the two products. Actually the only difference was that one had blotter paper and the other resin. Am I correct? Otherwise, they were similar.

Dr. HAYS. There is a great deal of difference.

Mr. NAUGHTON. I am not talking about the effect. I am talking about what went into them. Twenty percent vapona and related products and 80 percent inert ingredients.

Dr. HAYS. Mr. Naughton, it isn't necessarily what goes in. It is what comes out. It is the rate at which it comes out that bothers me.

Mr. NAUGHTON. What were you worried about? The fact more vapona might be released in the shorter period of time?

Dr. HAYS. Yes.

Mr. NAUGHTON. So you think under certain conditions vapona can be highly dangerous?

Dr. HAYS. Unless bound into a resin or material that prevents this from occurring. This is one of the purposes of many companies, to develop resin-type products.

Mr. NAUGHTON. But you don't have to worry about it being hung over an infant's crib for 3 months as long as it is a Shell product.

Dr. HAYS. I didn't say I am not worried about that. Didn't we just agree that this is a very logical step not to permit these to be——

Mr. NAUGHTON. But not concerned enough to take action to require the warning, at least up to date.

Dr. IRVING. Let me add at this time if I may, in the light of this discussion, we will notify Shell Chemical Co. to find and relabel, either by stamping present labels or by relabeling all of their strips that are now on the market.

Mr. NAUGHTON. How long do you estimate you will give them to—will it be the same timetable as Aeroseal?

Mr. ROSENTHAL. I think you should be commended for that action, very frankly.

Mr. FOUNTAIN. Are you satisfied this is the proper action to take?

Dr. IRVING. I am satisfied today it is the proper action to take.

Mr. ROSENTHAL. I think you should be commended for that.

Mr. NAUGHTON. Going to another aspect which involves the same type product, at Senate hearings last month Dr. Bayley made a statement which included the following comments:

> As a matter of routine procedure USDA scientists consult on questions of pesticide safety with expert authorities, whoever they may be, and with other agencies of the federal government.
>
> Critical use of pesticides on foods or feed are cleared by FDA under the Food, Drug and Cosmetics Act as amended. That agency has explicit responsibility for protection of food products. When a product could leave residues on foods, we delay registration until the applicant obtains the tolerance from FDA or deny registration if residues are left and no tolerance has been set.

Now, we are familiar with the procedures whereby a petition is submitted to FDA in connection with the asking of the tolerance for use of pesticides on raw agricultural commodities, but, of course, food in restaurants is not a raw agricultural commodity.

When a product such as lindane vapor is put into use, the directions call for the whole room to be filled with a vapor which will then kill insects.

The Shell No-Pest Strip works on the same principle. It fills the room with vapor. Was the proposed use of Shell No-Pest Strips and other similar commodities which are registered for use in restaurant kitchens where food is being served submitted to the FDA for the establishment of tolerance?

Dr. HAYS. It is my understanding, Mr. Naughton, that this is not the procedure. As you just mentioned, the requirement for tolerance is for raw agricultural products shipped in interstate commerce, and we have not filed any request to the Food and Drug to establish a tolerance for food in restaurants.

Mr. NAUGHTON. There is no tolerance for residues of insecticides on food in a restaurant, is there?

Dr. HAYS. No, sir.

Mr. NAUGHTON. Isn't it true that Shell's No-Pest Strip, and I would assume almost every product of this type, leaves a residue on food which is being prepared while it is in action?

Dr. HAYS. It is conceivable.

Mr. NAUGHTON. Don't tests submitted by Shell itself disclose the existence of a residue?

Dr. HAYS. In restaurant foods?

Mr. NAUGHTON. In foods, in kitchens, yes.

Dr. HAYS. I am not aware of such data. It could be that they have submitted data. I wouldn't know.

Mr. NAUGHTON. If there is no tolerance for such a residue, then it is illegal, is it not, under the Food and Drug Act?

Mr. BUCY. I think Food and Drug can answer that, but I don't know that Food and Drug regulates local restaurants.

Mr. NAUGHTON. I am assuming that it is in interstate commerce—maybe it is a restaurant in the District of Columbia where they are all subject to the act.

Mr. ROSENTHAL. The product is sold in interstate commerce.

Mr. NAUGHTON. Isn't this situation prohibited by the Food and Drug Act assuming the product is in interstate commerce?

Dr. HAYS. You are talking about the shipment of raw agricultural products in interstate shipment?

Mr. NAUGHTON. No, not raw agricultural products. I specifically excluded those. We understand that. I am talking about a use which is bound to result in a residue being deposited on food in a situation where interstate commerce is involved. Perhaps Mr. Bucy can answer that.

Mr. BUCY. I think probably you have the counsel for the Food and Drug Administration here who can answer what they considered to be adulterated.

Mr. FOUNTAIN. Did you get that question of Mr. Naughton's?

Mr. GOODRICH. Whether the use of vapona resulting in contamination of food while held for sale after shipment in interstate commerce would result in its adulteration. There would be a requirement of establishing for a processed food a food additive regulation permitting the residues that might be anticipated from this use of the pesticide.

Mr. NAUGHTON. In other words, if there is no tolerance, it is illegal, any residue.

Mr. GOODRICH. So long as the product is not generally recognized as safe, which of course the pesticide is not.

Mr. NAUGHTON. Are pesticides generally recognized as poisonous and deleterious substances?

Mr. GOODRICH. There are very few exceptions to that, all of which are listed in the regulation. In general that is true.

Mr. NAUGHTON. I understand that there are four tolerances that have been approved for use of vapona. Do any of those involve use in a restaurant or other situation where prepared food is exposed?

Mr. GOODRICH. My understanding is that those tolerances have been established for food stored in warehouses in packages and the tolerances were established for the use of this type of insecticide on warehoused materials, but the details of that can be taken up in more detail and better by Mr. Duggan.

Mr. NAUGHTON. Before those tolerances were granted was a legal opinion requested by those officials of FDA who granted the tolerance as to whether the law permits granting of a tolerance from a pesticide use such as this involving food other than raw agricultural commodity?

Mr. GOODRICH. Not specifically, but that document establishing the tolerance came through my office, and I did approve it.

Mr. NAUGHTON. You didn't make any specific legal analysis then of what constitutes a food additive under this condition. The law does prohibit, does it not, the addition of poisonous or deleterious sub-

stances to food except where it is required in the production thereof or can't be avoided by good manufacturing practice?

Mr. GOODRICH. This provision you are quoting was a part of the act of 1938. There was at that time an out and out ban against all poisonous and deleterious substances.

In 1958 Congress changed that policy by enacting the food additive amendment which allowed the safe use of additives which themselves might be classified as poisonous. They also took under control at that time chemicals of unknown or uncertain toxicity and directed that the agency establish tolerances that would be safe for that class of preparations.

Four years before that, in 1954, Congress had dealt with the pesticides on raw agricultural commodities, and in 1958 extended the rule applicable to pesticides that might appear in processed foods classifying them as food additives.

You will recall that there was a provision made in the food additives amendment that so long as—if a pesticide chemical appeared in a processed food because of its lawful use on a raw agricultural commodity it was not necessarily to get another tolerance.

Where a pesticide is used on a processed food, it comes under the food additive amendment, under our interpretation, rather than under the pesticide amendment, and the provision you quote was retained by Congress in 1958 to deal with accidental contaminations of food rather than with this purposeful use which is likely to result in food containing a residue of a food additive.

Mr. NAUGHTON. Doesn't section 346 of the code establish that when you add a poisonous or deleterious substance to food that if it is not required in the production of that food or it can be avoided by good manufacturing process, that you can't add it without making it unsafe automatically?

Mr. GOODRICH. That was true until the enactment of the pesticide amendment in 1954 and the food additive in 1958. We say that those enactments of the Congress authorize the establishment of tolerances for these two classes of chemicals and was an exception from the per se ban on poisonous and deleterious substances.

As the committee report indicates, 406 was retained to deal with accidental types of contamination where the poison could be avoided or was not required in production.

Mr. NAUGHTON. Has FDA established any tolerances for pesticide residues on prepared food in restaurants?

Mr. GOODRICH. Not specifically on restaurants, but there are some tolerances for pesticides on prepared foods. The issue of the restaurants, as I attempted to answer a moment ago, deals with whether or not the food is either in interstate commerce or is being held for sale after shipment in interstate commerce.

Most of it obviously is being held for sale after shipment in interstate commerce if it is being prepared in a restaurant kitchen because food isn't normally grown and processed in the same State. But as a matter of using our resources, the regulation of local restaurant sanitation and of local restaurant food preparation is dealt with as a local matter.

Mr. NAUGHTON. Hasn't the Public Health Service as a matter of policy objected to pesticide uses which involve continuous vaporization in closed areas where humans may be exposed?

Mr. GOODRICH. Yes; they have. And this is a part of the type of objections that were voiced here or were discussed here a little earlier this morning.

As the files indicate, as you yourself know, there has been a continuing objection to vaporization from lindane vaporizers going down through the years even before the enactment of the pesticide amendment in 1954 and before the food additive amendment in 1958.

That policy has been pursued right along. There was an objection to the use of the vaporizer in vapona in kitchens. That objection was made by the Public Health Service before that particular unit became a part of the Food and Drug Administration sometime last year and an agreement was reached that PHS would withdraw its objection if an additional labeling statement was included.

On the whole issue of vapona from the standpoint of safety, the Food and Drug Administration itself now has as one of its units this Public Health Service unit that has been responsible for reviewing labels.

And as you know from our statement which we are prepared to deliver later, we plan to go into that in more detail.

Mr. NAUGHTON. Just to clarify this, your position is that you would have the authority to grant a tolerance under the law. Could you submit something for us restating the positions that you have taken and the basis for them?

Mr. GOODRICH. Certainly.

(The statement supplied follows:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
OFFICE OF THE SECRETARY,
Washington, D.C., August 15, 1969.

Hon. L. H. FOUNTAIN,
Chairman, Subcommittee on Intergovernmental Relations, Committee on Government Operations, Rayburn Building, Washington, D.C.

DEAR MR. FOUNTAIN: When I appeared before your subcommittee on June 24, 1969, the question arose about FDA's legal authority to establish a tolerance for a pesticide chemical which might migrate from a No-Pest Strip and contaminate food held or being processed in an area where the strip was being used to repel flies and other insects.

Clearly the Pesticide Chemicals Amendment of 1954 is not applicable because it relates to pesticide chemicals in or on raw agricultural commodities.

The issue is whether the Food Additives Amendment of 1958 modifies the strict ban against unnecessary and avoidable poisonous and deleterious substances found in 21 U.S.C. 346.

The House Committee on Interstate and Foreign Commerce, in H.R. 2284, 85th Congress, second session, explained the coverage of the food additives amendment as follows:

> "* * * The legislation covers substances which are added intentionally to food. These additives are generally referred to as 'intentional additives.'
>
> "The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as 'incidental additives.'
>
> "The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.
>
> "On the other hand, substances which may accidentally get into a food, as for example, paints or cleaning solutions used in food processing plants, are not covered by the legislation. These additives are generally referred to as 'accidental additives' since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food. If accidental additives do get into food, the

provisions of the Food, Drug, and Cosmetic Act dealing with poisonous and deleterious substances would be applicable * * *."

Residues from a No-Pest Strip probably should be classified as "accidental additives." If properly used, there should be no reasonable expectation that this emitted pesticide would become a component of food.

If the pesticide strip were registered for a use in which there was a reasonable expectation of food contamination, the product would be a "food additive," but it is not clear that issuance of a tolerance would be permissible for the contaminant.

Yours very truly,

WILLIAM W. GOODRICH,
Food, Drugs, and Environmental Health Division.

Mr. NAUGHTON. Is it fair to assume that in view of the longstanding objections that PHS has had to continuous vaporization, you have no plans to grant a tolerance for the use of No-Pest Strips or similar type pesticides in kitchens even if you have the authority to do so.

Mr. GOODRICH. Bearing in mind PHS people objected to that, I would consider it unlikely that there would be such a proposal, but this is an issue which the Commissioner has stated will be taken up very shortly and a decision reached by July 1.

Mr. NAUGHTON. As long as no tolerance has been granted, then any residues that result from vapona strips render the food adulterated?

Mr. GOODRICH. Yes.

Mr. NAUGHTON. There is a question if a tolerance is granted as to whether you have the authority to grant it. You take the position you do, and others might take a contrary position.

Mr. GOODRICH. Correct. I think I take the position that the food additive amendment authorizes us to do that.

Mr. FOUNTAIN. The committee stands recessed until 2 o'clock.

(Whereupon, the subcommittee was adjourned to reconvene at 2 p.m.)

AFTERNOON SESSION

Mr. FOUNTAIN. Let the committee come to order.

Let the record show a quorum is present.

Mr. Naughton, maybe you ought to get into the record at this time some testimony concerning procedures for cancellation.

Mr. NAUGHTON. Mr. Bucy, I wonder if you could enlighten us a bit as to the procedures used when the Department decides to take steps to cancel a registration of a pesticide?

We have observed, with respect to certain products, that they appear to follow a sort of rulemaking procedure, where before initiating individual cancellation action they first advertise in the Federal Register, giving 30 days for comments, and then they indicate that in 90 days or so they intend to make this interpretation which will in effect render certain products unsafe for certain uses.

Could you tell us just how this rulemaking procedure fits into the cancellation procedures?

Mr. BUCY. In some instances it doesn't necessarily fit into it. I think it's a matter of where you do have substantial question with respect to whether certain warnings or certain instructions should be incorporated, they issue a notice of proposal in order to get the views and data as to what would be the best type of warning or instruction statement to require.

Here, in this area, I think it's an advantage to get it so you're not changing it, and then finding problems flow from not having all the facts. On the matter of cancellation, when it goes to a matter of a real threat to health or hazard, it being an interpretative statement, then I don't think they have to go through the notice, prior notice, and submission of views, and the period of time when it will become effective.

I think it is highly desirable and I think probably if it's a general rule, the Administrative Procedure Act requires that they publish it so that the public can be on notice generally, the interested members of the public, as to what the general policy is, both from the standpoint of safety and that if the general public knows what it is the interested parties are not investing money and taking steps to come up with some product that they find out later is no longer under that policy, going to be considered for registration.

Mr. NAUGHTON. In other words, the rulemaking procedure where you ask for the views of interested parties is useful in formulating positions, particularly where you might want to have a uniform understanding as to what certain terms meant when used on a label; things of this kind.

Mr. BUCY. That's right. Or if you need to, in a particular area, require specific requirements for that particular area of product, then it's desirable to get the views. I can see circumstances where it is desirable.

Mr. NAUGHTON. If the Department has determined and is satisfied in its own mind that a certain product is not safe, let's say because of an accident history or for some other reason, is any purpose served at all by going through the rulemaking procedure?

Wouldn't that just delay the eventual time of cancellation?

Mr. BUCY. I think if they have evidence that clearly shows this thing is a threat to the public safety, that they aren't required to give this 30-day notice.

In fact, they can on an ad hoc basis proceed with the cancellation. I think where it's a matter that is a broad use and a number of different people may be interested, that they should publish the general policy that they will not register any more in that area.

Mr. NAUGHTON. In a cancellation, say, where the question was a lack of effectiveness rather than safety, so imminent hazard didn't come into it, how long would that take? It starts out with a 30-day notice, doesn't it?

Mr. BUCY. Under the act it provides you serve notice that they have 30 days within which to take three alternatives. They may request that the matter be referred to a committee appointed with recommendations from the National Academy of Sciences; they may request a hearing; or they may correct the situation.

I suppose they can correct it. Maybe it's ineffective because they haven't the right formulation.

Mr. NAUGHTON. If it's a change in label that can be corrected easily.

Mr. BUCY. Yes. If they don't take one of those steps within the 30-day period, then the cancellation becomes effective.

Mr. NAUGHTON. For anybody who doesn't fight a notice to cancel, it is effective 30 days after notice is given. If they do elect to——

Mr. BUCY. If they do, and it is referred to a committee—I haven't got those figures before me, but I think it's 60 days that the committee,

by the act, should come in with a recommendation. Not over 60 days.

Mr. NAUGHTON. There can be one 60-day extension, can there not?

Mr. BUCY. The Secretary may extend the time if there is good cause for extension. After that recommendation is received by the Secretary, the Secretary has to determine the matter.

Without referring to the act, I think that is 60 to 90 days. I believe it is 90, that he has to decide. Then the party, if it is adverse to the party, they may then again ask for a hearing and you go to the hearing. At that time the committee's recommendation would become part of the record in the hearing, and you go through your regular hearing procedure.

Well, you end up having to give them a reasonable time in setting your hearing. It depends upon how long your hearing takes. When you get to the point of a final order, I would say you probably end up with, well, expedited, it would probably take a couple of months at the minimum if you went through the hearing process and probably longer than that.

Once that is completed, if it's still contrary to them, the party can appeal to the courts.

Mr. NAUGHTON. The question before the court in the event of appeal would not be whether the Secretary was right or wrong, but simply whether or not there was substantial evidence in the record of hearing to support the decision made?

Mr. BUCY. Yes. It would be decided on the record. It would be a review of the record. The court wouldn't substitute its judgment.

Mr. NAUGHTON. When a registrant receives a 30-day notice of cancellation, in the event it's a deficiency that can be corrected by changing the label, he may simply comply within the 30 days, which ends the matter.

Mr. BUCY. If he complies, that's the end of it.

Mr. NAUGHTON. If he doesn't respond, it's canceled. If he fights it he can ask for an immediate hearing, at which he would present evidence and the issues would be discussed and the Secretary would make a determination on the basis of that record.

Mr. BUCY. That's correct.

Mr. NAUGHTON. He has an alternative which would take longer, to ask for a review by a committee of the National Academy of Sciences?

Mr. BUCY. That's correct.

Mr. NAUGHTON. Then that report would come to the Secretary. The Secretary would make his determination with the report before him, and at that stage the registrant would have the option of asking for a hearing or not?

Mr. BUCY. That's correct. After the Secretary's final decision with the recommendation of the committee before him which was made, then the registrant would have the opportunity to request a hearing. That's correct.

Mr. NAUGHTON. If the registrant were interested in stringing out these procedures as long as he could, he could probably manage a few years, couldn't he, with all these appeals?

Mr. BUCY. We would hope that he wouldn't get away with a couple of years. I can see where when you add 30 days and 60 days to that, and some time intervening to constitute a committee, of course the Secretary has control over the 90-day period after he gets the recom-

mendation, he can act on that and expedite that 90-day period, but then when you get to the hearing again and then by the time you get through appeals, why——

Mr. NAUGHTON. Let's say a year would not be unreasonable. This is assuming that the Department was making reasonable effort to——

Mr. BUCY. Assuming you pressed it along. By the time you get up to that point, unless the fellow had a pretty good defense, which really raised a substantial issue, why, I would think the notice that he got out on it would certainly impair his operations with this product.

Mr. NAUGHTON. Now, during the period in which administrative procedures or litigation was underway, would the product normally stay on the market? The registration is still in effect.

Mr. BUCY. Yes; under the procedure prescribed, the cancellation doesn't take effect yet.

Mr. NAUGHTON. In the case of effectiveness, maybe you don't have any, but what procedures are there, if any, under which you can get a product off the market in a faster time?

Mr. BUCY. The act does provide for suspension, if there is an imminent hazard to human beings.

In that case it provides for an expedited hearing if you exercise your suspension authority.

Mr. NAUGHTON. But in that case, the product would be off the market or would be illegal if it were on the market as of the moment——

Mr. BUCY. The registration would be suspended. Therefore, you wouldn't have an effective registration at that time.

Mr. NAUGHTON. So you could issue a suspension order in the morning and start seizing products in the afternoon in the event that the manufacturer were not willing to recall them?

Mr. BUCY. Seizing them in the morning in the event that the product, in spite of compliance with the registration, still constituted a hazard to the public, you could proceed to seizure without going to your suspension proceeding, even.

Mr. NAUGHTON. Let me see if I have that straight. If it were a hazard, even if it were in compliance with the registration, and the registration weren't suspended, you could still seize it?

Mr. BUCY. Where it's handled in accordance with the prescribed instructions, and it still is an imminent hazard to the public.

Mr. NAUGHTON. So this would be a matter of determining that the instructions were such, that even if they were followed——

Mr. BUCY. That's right.

Mr. NAUGHTON. I don't know whether the label you were discussing this morning raised that question or not. It depends on the product, I guess.

Mr. BUCY. Each one of those is an ad hoc matter.

Mr. NAUGHTON. We were discussing this morning the removal of the Aeroseal Vapona Strip. Do you know of any instance, leaving that one aside for the moment, when the imminent hazard provision has been used?

Mr. BUCY. You mean from the standpoint of suspension forthwith? I don't have knowledge of it myself. Maybe the people administering the program have instances that they know of, but it hasn't come to my attention.

Mr. NAUGHTON. Now, if instead of proceeding directly to a cancellation procedure with respect to a type of product where there might be 40 or 50 of that product on the market, the Department did use a rulemaking type of device and asked for views to be submitted and then took a position after 90 days or so and put it in the Federal Register, that would have no effect whatsoever on the individual registration, would it?

Mr. BUCY. No. We would have to proceed against the——

Mr. NAUGHTON. You would still have to follow the same timetable?

Mr. BUCY. The procedure clearly indicates you have to notify the holder of the registration.

Mr. NAUGHTON. So if you were to use the rulemaking procedure in a situation where a safety hazard might be involved, you would just be losing that much time as compared with either invoking suspension or going through the cancellation procedure?

Mr. BUCY. Unless you made a finding and waived the notice for submission of views, as an interpretive rule you could issue it without the notice for submission of views.

Mr. NAUGHTON. In other words, if you wanted to get some of the advantages at least of the rulemaking procedure you could publish a notice in the Federal Register that due to the accident history of this product and the fact that it appears to be an imminent hazard to health, we won't accept any more registrations and are hereby suspending all existing registrations.

Mr. BUCY. Policy of the Department not to register this product for this use in the future and that it would take action against——

Mr. NAUGHTON. Cancellation or suspension if it were considered dangerous enough.

Mr. BUCY. A method of notifying the general public that this is a matter we have determined is hazardous.

Mr. NAUGHTON. Since you haven't used, so far as we can determine, the imminent hazard provision with the exception of such use as was made of it in the Aeroseal case, I guess you don't have a long body of precedent as to what does or doesn't constitute an imminent hazard.

Mr. BUCY. In that case you can have two or three reasons why you act. I assume Mr. Alford said he was motivated by the imminent hazard. Even if there wasn't an imminent hazard, they could have acted forthwith in any event in this particular instance because they were marketing a product which was not registered.

Mr. NAUGHTON. Is that not registered or misbranded?

Mr. BUCY. It was not registered because the product that he had a registration for was an altogether different product.

Mr. NAUGHTON. Well, it was vapona. The difference as I see it is between a blotter and——

Mr. BUCY. The end product is what is registered. The registration isn't issued for components. It is registered for vapona put up in this form.

Mr. NAUGHTON. You might have a situation where a product was both misbranded—anything that was not registered because it didn't conform to the registration would also be misbranded if the label bore the description on the registration.

Mr. BUCY. If it wasn't registered—that is right, it would be misbranded.

Mr. NAUGHTON. One other question. We had some discussion this morning of certain registered uses which involved a type of space vapor or space spray in which at least, I believe, there was every reason to believe that the residues are being deposited on food where these are used in establishments serving food in interstate commerce for which there is no tolerance and there is no indication of FDA intent to grant such tolerance.

Mr. BUCY. I understood that was still under consideration. At least there is no final action on their part toward issuing tolerances.

Mr. NAUGHTON. At the moment it would appear that a number of registrations involve uses which are adulterating food. Is there any quarrel with that conclusion?

Mr. BUCY. I don't know. There may be. I suppose the manner of handling that is if it is resulting in depositing a poisonous substance on food, you would have labeling requirements or warnings against its use in places where food was being prepared or stored.

Mr. NAUGHTON. In addition, even if the FDA has the authority to grant a tolerance as an additive, which I think is questionable, but assuming they do have it, they haven't granted it for any of these uses, have they?

Mr. BUCY. I don't know. I understood from Mr. Goodrich they had granted it for storage but hadn't dealt with the area of preparation of food.

Mr. NAUGHTON. There is quite a difference between food in a warehouse in a package which may be 3 months away from consumption by humans where the pesticide may be toxic but not persistent and a residue of a fairly highly toxic substance on a hamburger just before you eat it, isn't there?

Mr. BUCY. If it is persistent, it wouldn't be much difference whether it is in storage or in the kitchen or on the table. If it is not, why then, it would be a question of how rapidly the stuff went into consumption.

Mr. NAUGHTON. Getting to the legal aspect of it, clearly there was adulteration of food in connection with the uses of lindane. Your own tests showed that. I don't think there is any dispute about it.

The Shell people, in their own studies submitted, indicated that the use of their No-Pest Strip in restaurant kitchens will result in a measurable residue of vapona on the food.

Now, it seems to me that clearly this is adulterating food. That is against the law. What do you plan to do about it?

Mr. BUCY. I understood we had a cancellation proceeding pending at this time.

Mr. NAUGHTON. Against whom?

Mr. BUCY. Wait a minute. I am thinking of the other product.

Mr. NAUGHTON. You are not taking cancellation proceeding on that either, are you?

Mr. BUCY. It is a consideration of the labeling with respect to this product.

Mr. NAUGHTON. I would agree if the label bears the warning "don't use in kitchens or other rooms where food is prepared or served" that presumably you could use it in the garage or in a room where you don't keep any food and you shouldn't have the problem, but as presently registered the directions for use certainly say nothing at all warning the unwary user not to use it in the kitchen.

A lot of the boxes don't even warn him not to use it in the baby's bedroom.

What, if anything, do you intend to do about the adulteration of food that apparently is resulting not just from the No-Pest Strip but I would assume from any product which uses this same method of killing insects?

Mr. BUCY. Doctor Irving can tell you what he intends.

Dr. IRVING. We have an area here that we will have to look into further and we have already started looking into it.

I can't document the instances but the questions raised by Mr. Goodrich this morning and some of the discussion we have had indicate in the restaurant area, in the home kitchen areas, there is no jurisdiction on residues that occur in foods after they have arrived in the home.

Food and Drug is clear on raw agricultural materials in transit and warehouses. I believe the law is silent with respect to what happens to this food after it is prepared and produced in a restaurant or home.

The position I think we would take is this: If the Food and Drug Administration clearly says that any additional pesticide which would have to be specific as to kind and amount, is not tolerated in food after it is prepared and provided for use in a restaurant or in the home we would have to amend our labels or cancel depending upon the situation in that instance.

Mr. NAUGHTON. If they are not willing to grant a tolerance you will amend the labels to conform with their position?

Dr. IRVING. Yes, sir. But I will point out that it is complicated since we must go chemical by chemical. The food we have in our restaurants and homes already contains tolerable amounts of chemicals by FDA.

Some of the things we are talking about used in the home and restaurants may be the same chemicals already tolerated in foods in shipment. We would have to consider what came into the kitchen on the food in the first place and what has been added by the device since they came in the kitchen.

Mr. FOUNTAIN. The committee will take a short recess until we can answer a rollcall.

(Recess.)

Mr. NAUGHTON. Just to be sure the last point is clear, if the FDA takes the position that a particular use will result in food adulteration, will ARS then accede to the position of FDA and make such labeling change requirements as are necessary to change the situation so that food adulteration is not likely to result?

Dr. IRVING. We will do so.

Mr. NAUGHTON. How many products would you estimate are currently in use such as the No-Pest Strip and others which rely on emitting vapor of some type in a closed space where the adulteration of food, if used where food is prepared, would be likely?

Dr. HAYS. I would have to ask Mr. Alford.

Mr. ALFORD. I would say very few. There is a pyrethrum dispenser. There are one or two germicide dispensers, deoderant germicide combination. Relatively few products where it is continuous application.

Mr. NAUGHTON. Is DDVP, or vapona, considered safer than lindane?

Dr. IRVING. I defer that to the toxicologist.

Dr. HAYS. That is a matter that has not yet been resolved.

Mr. NAUGHTON. The registration of lindane was not suspended, was it?

Dr. HAYS. Suspended? No.

Mr. NAUGHTON. In other words, you are going through the regular cancellation procedures but no——

Dr. HAYS. This matter now is pending.

Mr. NAUGHTON. The reason for the concern about imminent hazard in the case of the Aeroseal was basically because it was felt that the blotter might release a larger amount of the vapona, DDVP, than the resin strip would which supposedly was emitting the vapors at a controlled rate.

Dr. HAYS. Yes.

Mr. NAUGHTON. So, your concern was that you might get a higher concentration of DDVP than you had tests for?

Dr. HAYS. That is correct.

Mr. NAUGHTON. Had you ever made any tests on the Shell No-Pest Strip to see whether in the 3 months these are supposed to be good for the rate of emission of vapona vapor is constant or whether or not there may be considerably larger quantities given off in the early times right after the box is opened than at a later time?

Dr. HAYS. We have not done it recently, but I would have to——

Mr. NAUGHTON. Have you ever done it?

Dr. HAYS. I would have to check to see whether it was done some years ago. It could well have been.

Mr. NAUGHTON. Have you taken samples of the No-Pest Strip, picked them up in the marketplace and tested them to determine whether the product now being marketed is, so far as you can determine by sampling, such that the vapona vapor will be released at a constant rate over the 3-month period which is the rate involved in any test you may have made?

Dr. HAYS. I said, to my knowledge, it has not been done recently. It may well have been done prior to my coming to the Division. I have not seen any such data.

Mr. NAUGHTON. So, you have no way of knowing from your own resources and your own tests that the Shell No-Pest Strip, if there might be some defect in manufacturing or a little extra heat if somebody hangs it near a lightbulb, might not result in a higher concentration of vapor than you planned for.

Dr. HAYS. All I can say is that the data submitted with this application was supported by data at varying temperatures and humidity. The data, in our opinion, was reliable scientific data.

Mr. NAUGHTON. Suppose somebody has a quite small room. Shell No-Pest Strips are designed to be placed in rooms of a thousand cubic feet minimum, are they not?

Dr. HAYS. Yes.

Mr. NAUGHTON. Suppose somebody has a tiny nursery room of 500 cubic feet. Is there any warning on the No-Pest Strip box that warns the user not to put it in a room smaller than 1,000 cubic feet?

Dr. HAYS. I don't know of any such warning not to; there is the precautionary statement or directions to use in a room of a thousand cubic feet.

Mr. NAUGHTON. Yes, but isn't there a danger in a room half the size where you would get twice the concentration?

Dr. HAYS. This matter really presents itself in the form of negative labeling. I am sure if we were to put on all labels all the things that you are not supposed to do there wouldn't be a label big enough to have this kind of negative labeling.

What we are interested in is what is the proper use of this particular pesticide.

Mr. NAUGHTON. Isn't it basic if you are concerned about concentrations of vapona higher than those on which you have tests, based on one strip per thousand cubic feet, to warn the user this may be dangerous if used in less than a thousand feet? No such warning is on the box, that I can find.

Dr. HAYS. This would be a misuse.

Mr. NAUGHTON. It says it is designed to be used—there is one other thing here. For the control of flies in animal buildings such as dog kennels and horse barns apply one strip per 1,000 cubic feet of enclosed area. Do you know of anybody with a 1,000 cubic foot dog kennel? If you put Shell's No-Pest Strip, one strip in a regular size dog kennel, aren't you going to get a much higher concentration than the 1,000 cubic feet we are talking about?

Dr. HAYS. I could visualize dog kennels of that size and larger.

Mr. NAUGHTON. Aren't there a number of circumstances which your labels don't warn against under which you could have a considerably higher concentration of vapona in a room even if the rate of emission is absolutely controlled?

If on top of that you may have a higher rate of emission in the early stages—I don't know that it does but you don't know it doesn't—I am suggesting if you are that concerned about Aeroseal, and I am not quarrelling with the very rapid aggressive action taken there, you should start thinking a bit about No-Pest Strip.

Mr. FOUNTAIN. Are you through?

Mr. NAUGHTON. Just one last question.

Does the Consumer and Marketing Service permit the use of vapona strips in meat processing establishments?

Dr. HAYS. No.

Mr. FOUNTAIN. Dr. Irving, is it true that the Department has taken the position that certain pesticides containing more than a specified percentage of arsenic compounds are unsafe for use in and around the home and that such use should no longer be permitted?

Dr. IRVING. Yes, sir.

Mr. FOUNTAIN. When did the Department first take this position?

Mr. ALFORD. August, 1967.

Mr. FOUNTAIN. What prompted the position?

Mr. ALFORD. It was a review of the accident reports as well as recommendations by the Public Health Service.

Mr. FOUNTAIN. Do you have any figures indicating the number of accident reports, Mr. Alford?

Mr. ALFORD. We have those. We don't have them here.

Mr. FOUNTAIN. Do you offhand know the approximate number?

Dr. HAYS. I think I can tell you, Mr. Chairman. From 1949 to 1967 there were about 186 accidents associated with the use of arsenic.

Mr. FOUNTAIN. So, it is true that there have been numerous accidents attributable to these compounds?

Dr. HAYS. Yes, sir.

Mr. FOUNTAIN. Have many of these accidents involved children?

Dr. HAYS. Yes, sir.

Mr. FOUNTAIN. Do you have any idea how many children?

Dr. HAYS. I don't know exactly how many children, but of the total number of human accidents there were about 27 fatalities.

Mr. FOUNTAIN. Twenty-seven fatalities.

Dr. HAYS. Yes. Some were suicide. Some accidental.

Mr. FOUNTAIN. Do you happen to know how many were suicide?

Dr. HAYS. Offhand, I think there were probably in the neighborhood of eight or 10.

Mr. FOUNTAIN. Mr. Naughton just handed me a document indicating there were 39 fatalities, all of which involved accidental ingestion. In addition, there were three suicides.

The breakdown shows: Skin contact, four accidents. Victims, four. Inhalation and skin contact accident, two. Victims, four. Inhalation accidents, one. Victims, one. Unknown, two in each category.

Now you first took the postion they were unsafe for such use you say August 1, 1967. How close are you to getting these arsenic compounds out of the market for use around the home?

Dr. HAYS. We have referred this matter to the National Academy of Sciences. There seems to be a difference of opinion as to our action in this regard based in part upon the types of compounds, the chemistry of arsenic and its compounds. And in order to resolve this matter we have referred it to the National Academy of Sciences.

Mr. FOUNTAIN. Now, you say there seems to be a difference of opinion about it. Where is that difference of opinion?

Dr. HAYS. It lies principally, Mr. Chairman, in the type of compound.

There is, first of all, a compound known as sodium arsenite. This is in liquid form. The second compound involving arsenic is arsenic trioxide in granular solid form. There is some question as to the degree of toxicity as it relates to the arsenic trioxide as compared with sodium arsenite.

Mr. FOUNTAIN. The summary figures for human poisonings by arsenic trioxide shows 16 accidents and two suicides. Victims, 39. So, the arsenic trioxide, you had almost as many as you did in the other.

An then you have a listing of other arsenic compounds and arsenic undetermined: 102 accidents; 108 victims; seven fatalities. Inasmuch as you made the decision on August 1, 1967, that those pesticides containing more than specified percentages of arsenic compounds are unsafe for use in and around the home, why has it taken so long to make a final decision? What has happened in the meantime?

Dr. HAYS. I might say first of all that most of the products containing sodium arsenite have been removed from the market. The principal issue again is this matter of arsenic trioxide. We have had additional data submitted to us by the registrant indicating that their evaluation of the toxicity of this material is not, in their opinion, of the same degree as we place upon it.

Therefore, they have submitted additional information, asking us to review it. We have done it.

Mr. FOUNTAIN. You say you have called upon the National Academy of Sciences to make a study of the matter. Have you already made this request or are these plans?

Dr. HAYS. The letter has gone to the administration for transmittal to the Academy.

Mr. FOUNTAIN. It has not gone out yet?

Dr. HAYS. It hasn't been signed yet.

Mr. FOUNTAIN. Who is supposed to sign that?

Dr. HAYS. That would go to the Administrator.

Mr. FOUNTAIN. Who is the Administrator?

Dr. IRVING. I am.

Mr. FOUNTAIN. If this is requested by USDA, who pays the cost?

Dr. HAYS. We have a working relationship with the Academy through the Advisory Center on Toxicology. The industry in this instance didn't request a hearing, and we took the initiative to ask the Academy, through this agency, to make a review.

Mr. FOUNTAIN. So, you would pay the cost?

Dr. HAYS. Yes, sir.

Mr. FOUNTAIN. If the cancellation action were brought and the manufacturers asked for a study by the National Academy, they would pay the cost?

Mr. BUCY. They could be required if the Academy ruled contrary to their contention.

Mr. FOUNTAIN. In other words, the manufacturer would pay it if the study didn't support that position?

Mr. BUCY. Yes.

Mr. FOUNTAIN. The question is running through my mind as to why USDA should assume the cost of the study under any of the circumstances. Would you care to comment on that, Doctor?

Dr. IRVING. We go back to the fact that this whole operation we are discussing today is supported by appropriations to the Department of Agriculture, Pesticide Regulation Division. Some of this money we spend in-house on staff we hire. We have the option to procure advice and service through other means, through contract, through grant, and through arrangement with a body like the National Academy of Sciences.

I believe it is a legitimate use of our funds to seek such advice where we feel we need it to arrive at a judgment.

Mr. NAUGHTON. This will benefit the manufacturer of the particular product involved, won't it, in that you are assuming a cost that had you taken cancellation action they would have to assume or might have to?

Dr. IRVING. To a certain extent, you are correct in this, if this were the only point at issue. I think the question is: We want to learn.

Mr. NAUGHTON. Do you have the kind of money that you can afford to spend on tests which, if the manufacturer wants to keep this product on the market, he himself can assume the responsibility for paying?

Dr. IRVING. No, sir. The instances in which we do that are very few and far between. As I say, we do this when we feel this will add to our total knowledge for disposition of, not only this case, but others.

Mr. NAUGHTON. How long will it take, approximately, for this study?

Dr. HAYS. We have asked them to give it their immediate attention. I suspect it will take no longer than 30 days.

Mr. NAUGHTON. If they come back in with an adverse report in 30 days, where are you? How much closer to cancellation are you than you are today?

Dr. HAYS. Of course, Mr. Naughton, this is the point at issue, and we need to have this matter resolved before making final judgment.

Mr. NAUGHTON. On August 1, 1967, you published and sent a notice to manufacturers, formulators, distributors, and registrants of pesticides containing sodium arsenite and arsenic trioxide. It said, in effect, that products containing these substances have been involved in numerous accidents involving children and domestic animals and that experience has shown previous labeling requirements for products containing more than 2 percent of sodium arsenite or 1½ percent arsenic trioxide bearing directions for use around the home have not been adequate to protect the public.

Now, you indicated then that you were going to proceed to take action to require limitation to those amounts. This was almost 2 years ago. How much closer are you to getting these products off the market, assuming your judgment in deciding they were too dangerous, is upheld, than you were 2 years ago? Are you 1 day closer in terms of procedure?

Dr. HAYS. This is a matter where we still would ask the Academy for advice.

Mr. NAUGHTON. Why didn't you ask it 2 years ago if you thought that was the proper step?

Dr. HAYS. Largely on the basis that the manufacturer felt that they had supporting data for their position and, in all fairness, we gave them the opportunity to submit this data, to review it.

Mr. NAUGHTON. What about the Aeroseal people? Did they have supporting data? Did they contend their product was safe and you were wrong?

Dr. HAYS. They didn't have any data.

Mr. NAUGHTON. Of course, they only had 4 days. I guess it would be a little tough to accumulate any—please don't regard me as criticizing getting the Aeroseal product off the market. I am not. I am comparing the action taken, which was aggressive and fantastically swift, with the record on arsenicals where you have an accident history, where you decided yourselves 2 years ago this product was dangerous for use around the home—I don't know what you have been doing for 2 years, but you still, if you want to take this product off the market after that study comes back, have to start all over again with the procedure of cancellation——

Dr. HAYS. We are not taking the product off the market.

Mr. NAUGHTON. For use around the home.

Dr. HAYS. We are limiting its use. I think that is a little different than the Aeroseal.

Mr. NAUGHTON. You want to get it where it won't be poisoning children?

Dr. HAYS. That is correct. I think there is a difference between limiting the uses and canceling a product in toto.

Mr. NAUGHTON. If this study comes in in 30 days and it is adverse, to start off with you pay for it instead of the manufacturer. Then

you have to go through all the procedures set forth in the cancellation requirements all over again, don't you? Don't you have to give a 30-day notice to the company of cancellation?

Dr. HAYS. They will be given a final notice.

Mr. NAUGHTON. The law provides they, as a matter of right under this type of cancellation procedure, can request a study by the Academy. Suppose they request their own study by the Academy?

Dr. HAYS. That is a matter I hadn't considered.

Mr. NAUGHTON. Are you sure you might not have to go through the whole procedure again? If another adverse report comes in, it will be another year and a half or 2 years. How many children do you suppose have been poisoned by these arsenicals during the 2 years in which you have been asking for the views of industry? Or I should say probably the specific company, whichever one it is, that manufactures this product?

Dr. HAYS. We have no recent reports of any injuries.

Mr. NAUGHTON. Of course, you don't get reports, do you?

Dr. IRVING. The company's claim is, there have been none.

Mr. NAUGHTON. So, do you take their word for it? Do you ask the poison control centers?

Mr. FOUNTAIN. What are your sources of information for accidents?

Dr. IRVING. In all of these products, the burden is on the one who presents a product for registration to present all the data necessary to satisfy us so that we can register it. All of the data.

The source is the one who is requesting registration. Our consideration of that data is in the light of all the published information available on compounds similar to the compound under question, used as proposed, so that we rely on not only the registrant's information, but all the other available information in order to make our judgment.

If there is a lack of information, the proponent of the product is asked to produce additional information. That was done in this case, too.

The Medical School of the University of Utah developed some of the figures on arsenic that we are considering. They are at variance with our own judgment on the basis of published information on related compounds. For that reason we are asking for a resolution of this question by the National Academy of Sciences.

Mr. FOUNTAIN. If a 6-year-old girl in my hometown got hold of arsenic today and took it and was killed, is it likely that a report of that death would reach you?

Dr. IRVING. I think it is highly likely.

Mr. FOUNTAIN. How would it get to you?

Dr. IRVING. I think it would be reported in the locality, and those types of reports we follow up on in our accident investigation surveys.

Mr. FOUNTAIN. Where would you get the report from?

Dr. IRVING. From all of the sources of information that pertain to the case. The hospital, the doctors.

Mr. NAUGHTON. Do you have any arrangements with hospitals to receive reports? You have no arrangements to receive reports from hospitals, do you?

Dr. HAYS. Not directly.

We have, as we mentioned, the source of the Poison Control Center in Washington.

Mr. NAUGHTON. But you don't utilize that data.

Dr. HAYS. We made a very thorough study of the records of arsenic with the Poison Control Center.

Mr. NAUGHTON. What do they show?

Dr. HAYS. Then we made our own investigations from correspondence and any reports we received. We have also made a survey of some of the State hospitals, and we have also met on numerous occasions with the State pesticide control officials. And we have written to many of the officials for reports of any accidents associated with arsenic. So, we have covered almost all of the 50 States through the State officials.

Mr. MYERS. Dr. Hays, all of those steps you just described, weren't they taken some time ago for purposes of getting your August 1967 release published?

Dr. HAYS. Yes.

Mr. MYERS. In other words, during 1968 and so far in 1969 you haven't been updating your arsenical accident history, have you?

Dr. HAYS. We asked every one of these State officials to——

Mr. MYERS. For instance, the poison control centers, all the sources, the hospitals, the doctors? The information we obtained from your files show accidents on arsenicals stopping at 1967.

Dr. HAYS. No, I think we have sent a representative to the Poison Control Center to look at the records.

(The Pesticides Regulation Division subsequently submitted the following additional statement:)

The Division has been updating the arsenical accident history through 1968 and into 1969.

Periodically we have received reports of pesticide accident investigations from the Plant Pest Control Division and our field staff. Our records show that 16 accidents involving arsenicals have been investigated since 1967. Seven of these accidents involved 21 humans of which eight died. None of the arsenical products involved were for home use.

We have obtained additional information from the Poison Control Division, Office of Safety, Food and Drug Administration. Since the beginning of 1968, we have received a report of one accidental fatality involving an arsenic poisoning. Additionally, there were three suicidal fatalities.

In addition, we have reviewed the 1968 Poison Control records for nonfatal accidents. The number of reported accidents due to arsenic is complicated by the fact that the product is not specifically identified and too many cases were judged solely on the basis of symptoms and product name.

(NOTE.—Further inquiry by the subcommittee disclosed that more than 300 poisonings potentially involving arsenicals were reported to the Poison Control Division during 1968. The subcommittee inquiry also disclosed that PRD representatives did not visit the Poison Control Center to obtain the information on which the above statement was based until July 7, 2 weeks after the subcommittee hearing.)

Mr. MYERS. Was that the information submitted to Dr. Done in Utah for his purposes?

Dr. HAYS. No, sir.

Mr. MYERS. In other words, you have 1967 through 1969 arsenical poisonings throughout the country?

Dr. HAYS. I don't know that we have the reported cases. I said that we have asked every State official to alert us to any recorded injury or accident associated not just with arsenic, but with all pesticides.

Mr. FOUNTAIN. Who are the State officials?

Dr. HAYS. There are State officials in every one of the States known as the State pesticide control officials. There is the Association of American Pesticide Control Officials. We meet with these people annually. We have met with them throughout the country at our regional meetings to which all of the officials have been invited to participate in our activity. Accident is a major part of our review; there experience within the States.

Mr. NAUGHTON. All that information is included in the 152 reports that you received in 1968 that you thought were fairly complete and working very well, wasn't it?

Dr. HAYS. Yes.

Mr. NAUGHTON. By comparison, it turns out to be only a very small fraction of the actual number of accidents that occurred. You are not still contending that you really have a good accident reporting system, are you?

Dr. HAYS. I am sure, Mr. Naughton, there is plenty of room for improvement.

Mr. NAUGHTON. You would be willing to recognize there could be a number of arsenic poisoning cases you wouldn't hear about?

Dr. HAYS. Yes, and we are making every effort to try to improve this matter of accident reporting.

Mr. NAUGHTON. How long will it take? Can we assume that if another product such as arsenic or more dangerous comes up tomorrow and you get an accident history on it that you will publish a notice and 2 years later you will still be talking to the company about information? If they aren't able to satisfy you, you will pay for a study that might help them out of their problem. Why all this solicitude for the company? Why not simply send them a notice of cancellation and if they can prove their product is safe, all right.

If they can't, get it off the market around the homes. The burden of proof is on them, isn't it? Why are you assuming it?

Dr. HAYS. I can say we shall do everything possible to expedite this matter.

Mr. FOUNTAIN. Dr. Irving, I think he is asking you a good question.

Dr. BAYLEY. There is a difference here between this and some of the others. A medical school has provided additional data which raises a question regarding the differences between these products in terms of their safety or lack of safety.

Mr. FOUNTAIN. You mean there is some question about whether or not arsenic trioxide is safe?

Dr. BAYLEY. Or not safe. They have raised the question with additional data that it is a safe product.

Mr. FOUNTAIN. What kind of data can they submit to show this is safe around the home?

Dr. BAYLEY. Data with animals. Toxicological data. It is this issue that we are trying to resolve through the National Academy. In this case, it isn't just a professional opinion. There has been data provided. We believe the medical school's information should be respected.

Mr. NAUGHTON. Can you explain to me the difference in treatment of the two companies here? With the Aeroseal company you had doubts and in 4 days took action to get that product off the market in terms of imminent hazards.

You don't have doubts about the arsenicals. You have an accident

history. You may have a lingering doubt that maybe an exception could be made for this product. It's been 2 years.

When did they submit this information that caused you to have some doubt that maybe it's not as dangerous as some of the others?

Dr. HAYS. About July of 1968.

Mr. NAUGHTON. All right. That's a year ago.

Dr. BAYLEY. They submitted some more this spring.

Dr. HAYS. Following this there were——

Mr. NAUGHTON. And I'm sure they will be happy to keep on submitting information indefinitely as long as it will keep their product on the market. Hasn't that occurred to you?

Dr. HAYS. I'm sure there will come a point——

Mr. NAUGHTON. How many more poisonings of children will it take?

Dr. HAYS. We would hope none.

Mr. NAUGHTON. But you are willing to take the chance.

Dr. IRVING. Since we are talking about the poison control center, and we on this side of the table have been talking loosely in numbers, I think this might be a point to insert some figures from the poison control center report of November 22, 1968, which has the number of deaths due to accidental poisoning by types of solid and liquid substances, people of all ages in the United States, 1957 to 1966.

The number of deaths due to accidental poisoning from arsenic and antimony compounds, which includes more than arsenic and it is not broken down, varies annually from a low of 23 to a high of 39.

I cite that to give us a point of reference from the records of the poison control center.

Mr. FOUNTAIN. Is there anything else in the report that might be helpful?

Mr. NAUGHTON. That is the number of reports they have. They don't feel their data is complete, do they? They indicated they get one out of every eight or 10 reports. Probably higher on fatalities.

Dr. IRVING. That would be for them to define. I'm not privy to the system by which they collect their data. I am simply reading from their report, which is not qualified.

Mr. NAUGHTON. You indicated some of these products have been removed from the market. Those were removed voluntarily by the manufacturers, weren't they?

Dr. HAYS. Yes.

Mr. NAUGHTON. How many companies are there that still want to market these products? Anybody besides the Pax Co.?

Mr. ALFORD. There is one other company that expressed an interest in continuing marketing.

Mr. NAUGHTON. If Pax could keep theirs, the other company wants to ride along with them?

Mr. ALFORD. They want to regardless of that.

Mr. NAUGHTON. If you can't get the action resolved on something with an accident history like this in 2 years' time, as a matter of fact you haven't even gotten the process started in 2 years' time, what hope is there to expect that you will ever be able to get any registrations canceled?

Dr. HAYS. I think our record on cancellations of materials is good hope that we will move forward and if the report of this committee

is contrary, or supports the proposition I'm sure it will be canceled immediately.

Mr. NAUGHTON. I can reasonably predict the committee will not look favorably at the 2-year delay in this.

Now, you indicated that the Pax people claim that their product does not cause accidents?

Dr. HAYS. That's correct.

Mr. NAUGHTON. But you did find accidents attributable to that product, did you not?

Dr. HAYS. Yes. We think that there are reports of the Poison Control Center that are accurate, although again, in these reports it is difficult to precisely identify the specific product.

Mr. NAUGHTON. Well, let me read from a letter of March 18, 1969, which you sent, or your name is signed to it, to the Pax Co.

Quoting from it, you are telling the Pax Co. that:

> Our action to restrict these uses was based on the record of accidents involving such products. The products manufactured by the Pax Co. were involved in a number of accidental ingestions. Although none of those reported resulted in fatalities, we cannot disregard them as being insignificant.

Now, Dr. Irving, are you going to approve the payment for a study by the National Academy of Sciences for the benefit, as I see it, of the Pax Co. from the taxpayers' funds, or will you go through the cancellation procedures and let them pay for it if they want it? Unless it comes out in their favor.

Dr. IRVING. I believe, subject to correction by someone who knows definitely if it's different, that this is a continuing service of the National Academy of Sciences that we draw upon as needed. This was an instance of one of those needs. We avail ourselves of this on a continuing basis. I don't know what it does cost, but we can get that figure for you.

Mr. NAUGHTON. What other company have you ever done this for?

Dr. HAYS. This is the first one.

Mr. NAUGHTON. So it's not a continuing basis to pay for this type of thing, where the benefit is obviously to that of an individual company which wants to keep its product on the market.

Haven't they had long enough already, without being even subjected to cancellation procedures? What do you think the hearing procedures provided for in the cancellation law are for?

In other words, there is a procedure that is set up. You send a 30-day notice. The company sends in any information which would tend to show differently. They can ask for a hearing and have a full chance to put their story in the record. They can ask for a study by the National Academy of Science—they might have to pay for it if it doesn't support their position, but if the recommendation of that committee is that this product is safe, the Secretary can use that, he can decide, after going through these procedures that this product is safe.

But why leave it hanging for 2 years without even starting? Do you have any response to that question?

Mr. FOUNTAIN. It's sort of the same question which you have been asking, which they haven't been able to——

Dr. IRVING. I think it's relatively different, to look back in perspective on the things we have done in this particular instance, and to experience the situation as it unfolded.

We always hope in these situations that the next piece of data we get will be convincing—there will be no question in our mind about it. That often occurs.

The history of an application requires frequent going back to the manufacturer to supply additional information. Often the process takes a matter of weeks, but we eventually do get the information that convinces us.

We are reasonably confident that we can secure information from various sources that will permit us to come to a judgment. In this case, this has not been true, right up to the present time.

Now that we have the information supplied by the manufacturer, supported by information coming out of the University of Utah Medical School, it differs with our judgment. But it's an honest difference of judgment between scientists, theirs and our own scientists.

We figure at this stage, the way to do this is get it submitted to an impartial jury of experts to give us an answer on this as a matter of principle. It would apply not only to Pax but to anybody else from then on who makes application to use these things in excess of the 2-percent tolerance we have established.

Mr. NAUGHTON. Are you suggesting that anybody who has a cancellation proceeding from now on, where it's a question of safety, you will not bring any cancellation action at all, until you have arranged for and paid for a study at the National Academy of Sciences?

Dr. IRVING. No, sir.

Mr. NAUGHTON. Why did Congress enact that law?

Dr. IRVING. The answer to your question is "No." Only in those basic cases where we are unable to come to a conclusion ourselves.

As we indicated, this is the first we know of—at this table—where we availed ourselves of that.

Mr. NAUGHTON. Your personal conclusion was that this was not safe, wasn't it?

Dr. IRVING. Yes, sir.

Mr. NAUGHTON. That was made a long time ago?

Dr. IRVING. Yes, sir.

Mr. NAUGHTON. Have you changed your opinion since?

Dr. IRVING. We are willing to change our opinion, if there is a body of information brought to us by the National Academy of Sciences which causes us to change our opinion.

Mr. NAUGHTON. Why not go through the regular procedure and let the company prove it's safe if they can?

Mr. FOUNTAIN. Well, we will finish up with that with one or two more questions.

The Public Health Service endorsed your decision; did they not?

Dr. HAYS. Yes.

Mr. FOUNTAIN. I believe it was by a letter dated December 15, 1967. This was several months after you made the decision.

You, Dr. Hays, got a letter from Dr. Harris, Chief of the Registration Section, Pesticides Program; they submitted their comments and said in the immediate paragraph:

It is our considered opinion that this proposed interpretation should be revised to include all concentrations of these arsenicals and not be restricted to concentrations above 2 percent. We see no evidence that products containing 2 percent or less of these chemicals would be safe. On the contrary, we estimate that it would be possible for a 30 pound child to consume many times the lethal quantity of a product containing 2 percent of sodium arsenic.

The second objection is the apparent lack of evidence that these products are necessary for the control of household insects. We base this on discussions we had with research people in the U.S. Department of Agriculture and also with experts in the Pesticides Regulation Division. We are reminded of an admonition in the President's Science Advisory Committee report with regard to the registration of hazardous products which states in part: "As a corollary to cautious registration of new pesticides, more hazardous compounds might well be removed from the market when equally effective and less hazardous substitutes are found. The panel believes that it is necessary to modify the use of some especially hazardous and persistent materials now registered."

We would be most happy to discuss with you in more detail our opposition to continued registration of these hazardous products that are to be used and stored around the home, as well as other similar products not included in this proposed interpretation.

Did you have discussions with Dr. Harris or anyone else in the pesticides program, registration section of the pesticides program of the Department of Health, concerning this subject?

Dr. HAYS. I don't know that I had.

Mr. FOUNTAIN. After the date of this letter?

Dr. HAYS. No.

Mr. FOUNTAIN Anyone else here?

Dr. HAYS. The only reference I recall, Mr. Chairman, was a letter to the Public Health Service asking to reaffirm their position in regard to this objection.

We have received a response to that letter, saying that they would, if I recall correctly, they would like to review the data that was submitted by the Pax Co., and perhaps wish to comment on it further.

We have not received any further comment as yet. That was a letter about a month ago.

Mr. MYERS. This information that you have been referring to that you received from Pax, when did you receive new data, data subsequent to let's say, July 1968? The data you are referring to we know was received during 1969. I believe in January, March, and April of 1969.

It involved certain information supplied to PRD from the medical school at Utah, is that right?

Dr. HAYS. Was that in 1969? I don't have these dates.

Mr. MYERS. We are supplied with three pieces of information. On January 3, 1969, March 4, 1969, and April 7, 1969.

Dr. HAYS. That is correct.

Mr. MYERS. The notice in the Federal Register was published in July 1968 and was to become effective within 90 days. That was published in July 1968, subsequent to the August 1967 release, which had already been discussed here.

The July 1968 release was done after reviews and evaluations of comments from industry and anyone else who wished to comment.

There was an extension of that 90-day period rather than permitting the July 1968 release to become effective and I was wondering what information was received by ARS between July 1968 when they extended the notice in the Federal Register rather than permitting it to become effective, which got us——

Dr. HAYS. I don't recall precisely the extent of the data submitted in that period with the exception of a review of their experiences with the marketing of their product in several States.

Mr. MYERS. Doctor Hays, was any new data supplied during that period? Any data you hadn't seen prior to July 1968?

Dr. HAYS. I am not sure whether that data which was submitted in 1968 was exactly the same as that submitted earlier.

Mr. MYERS. Would anyone know here today? Mr. Alford, perhaps? Anyone directly involved in these files?

Mr. ALFORD. No; I can't answer that.

Mr. MYERS. Could we ask for any data that was new that could be supplied for the record between July and October 1968?

Mr. FOUNTAIN. Will you supply the subcommittee with that data? Any new data?

Dr. HAYS. Yes.

(The subcommittee was subsequently advised that the only data submitted between July 1968 and October 1968 was essentially the same as that previously submitted.)

Dr. IRVING. Mr. Chairman, may I add something here? In the references made earlier to cancellations, we have been talking about relatively few products here in detail today. I have here the annual report of the Pesticide Regulation Division ending June 1968. It is similar to the annual report which will be issued soon covering the period up to this June 30. It shows that our annual workload is 37,402 total applications processed; new products registered are 4,666; labeling amendments or revisions accepted, 10,961; products canceled, 16,376.

Mr. FOUNTAIN. How much personnel do you have in this particular area?

Dr. IRVING. In the total division, about 250 personnel.

Dr. HAYS. 125 in the Washington area.

Dr. IRVING. Concerned with registration. That was the chairman's question.

Dr. HAYS. Total of around 50 people which is——

Mr. FOUNTAIN. How many applications for registration can one man process in a day?

Dr. HAYS. That is difficult to——

Mr. FOUNTAIN. On an average.

Dr. HAYS. Mr. Alford, do you have any idea?

Mr. FOUNTAIN. I realize it will be an approximation.

Mr. ALFORD. The principal applications are new uses which require data review or additional products which are already supported. So, if it is an additional product which is already supported, the average reviewer can do from 15 to 25 per day.

If it requires data review of course it may take a number of days on one application, or it may be less.

Dr. HAYS. If it involves a petition, Mr. Chairman, I personally spend 12 to 14 hours reviewing a single petition.

Mr. FOUNTAIN. Mrs. Dwyer?

Mrs. DWYER. No questions.

Mr. FOUNTAIN. Mr. Copenhaver?

Mr. COPENHAVER. No questions.

Mr. NAUGHTON. A question has been raised with us by some of the people who are interested in pyrethrums, which they contend are

harmless and safe to eat and quite as nontoxic as any pesticide can get. Is it true that pyrethrums are, as these things go, much safer than most other pesticides?

Dr. HAYS. It all depends on what you mean by safe.

Mr. NAUGHTON. I don't think any of them are safe.

Dr. HAYS. That is right.

Mr. NAUGHTON. But relatively less dangerous. Put it that way.

Dr. HAYS. All right.

Mr. NAUGHTON. Now, their particular concern is that apparently under present regulations pesticides for which the active ingredient is essentially pyrethrums and other substances which are not in themselves toxic have been allowed to carry the label description nontoxic to humans and pets and it is their belief this is a great help in sales of products containing pyrethrums.

Their consumer surveys show the housewives don't know what pyrethrums mean but know what nontoxic means and this perhaps is the major single element which goes into their choice.

They are concerned because under a proposed revision of terms to be used on labels, apparently the term nontoxic will be eliminated and that any substance which has a toxicity range of LD–50 on up to infinity or the highest range that you would get would all be classed together.

They claim there is merit in promoting or at least allowing the use of pyrethrums, if they are safer or less dangerous than the other pesticides, to be promoted through some labeling which will at least segregate it or separate it from relatively much more dangerous pesticides?

Dr. HAYS. Well, Mr. Naughton, in the first place if we are thinking in terms of lethality of a product, then I would agree that pyrethrum is certainly of a lesser toxicity than other pesticides. On the other hand, as a toxicologist, we are thinking of other effects of pesticides, or any chemical, any drug.

Then such a definition would have no meaning. I don't know of any chemical that can't and doesn't produce some physiological effect.

If you look at the publications in the area of pharmacology and toxicology, we look at it as any effect produced by a chemical is an adverse effect, or a physiological one.

Now, as I listened to the discussions this morning, it would seem to me that your concern and ours is one of protecting the public and it is my belief that all economic poisons should have some precautionary statement.

I cannot subscribe to a term, "nontoxic to humans and pets," when, indeed, there is an established LD–50 for pyrethrum that is evident in itself, that it cannot be classified as nontoxic. It is a toxic compound.

For many years pyrethrum had produced adverse effects among the human population in what we term as allergenic response. It had a high degree of allergenicity.

This, Mr. Chairman, is a manifestation of toxicity. For this reason it seems to me that if there is a certain segment of the population that is sensitive to pyrethrums we can no longer condone the use of the words "nontoxic to humans and pets."

So, in the interpretation 18 we have felt the need to have an open end in the category 3 that would require at least some precautionary statement for all economic poisons.

Mr. NAUGHTON. What is the LD–50 for pyrethrums; I have been told it is 16 to 20,000. Does that sound right?

Dr. HAYS. No. I don't recall what it is but I am sure it is not that.

Mr. NAUGHTON. Just to give you food for thought, their contention and complaint is that pyrethrums are relatively very expensive substances. I think it was $40 or $50 a pound—per hundred weight, maybe—but anyway a hundred times more expensive than DDT and other types of pesticides which pyrethrum people claim are much less desirable and more dangerous.

They are much concerned that if all compounds in a very wide range, some of which may be much more hazardous than others, all have to be labeled slightly toxic that they then lose any sales advantage whereby they are able to promote their product as less dangerous than others and this is likely to cause, in their view, a switch of people from pyrethrum to what they call more dangerous pesticides.

Now, regardless of whether or not the word "nontoxic" is used, would you subscribe to the idea that if a particular pesticide is established to be less dangerous, less hazardous than others, that they ought to be able to put something on the label which would indicate that relatively, if the housewife is looking for the safest product to buy to kill insects with, that this is it, still warning that here is danger associated with any insecticide.

Dr. HAYS. Of course pyrethrum has limited usage. It doesn't control and eradicate all pests. It has an extremely limited usage.

What about all of the other materials that are necessary for control of other insects?

Now, my responsibility is in safety and effectiveness and not in sales. I have not subscribed to the idea that such a term really has much to do with sales anyway.

Mr. NAUGHTON. Well, I would be happy to supply you with a copy of their marketing report. I don't believe it is confidential. It isn't now.

Dr. HAYS. The second point I wish to make is that such a term, Mr. Chairman, only encourages misuse. Here is a product, plain as can be, nontoxic to humans and pets. Therefore, you need not take any precautions whatsoever. There it says nontoxic.

I simply can't subscribe to that. As a matter of fact, we had this problem posed to us on the continuous vaporizers of pyrethrum, and we had long discussions with the manufacturer of this particular type of material and they finally agreed that this is not a good term and agreed to change it to what I believe is more of a true scientific evaluation that it is of minimal toxicity to humans.

I believe I can truly, as a scientist, defend that term, "minimal toxicity," but surely not "nontoxic." That term appears on pyrethrum dispensers "minimal toxicity to humans and pets."

It hasn't hurt their sales apparently, though that was one of their original arguments. Now, they have no reason to say that because you required this our sales have gone down. That has not been the case.

So, I think if we want to give the public adequate protection we ought not to encourage nor condone misuse by mislabeling.

Mr. NAUGHTON. I don't suggest that all appropriate warnings should not appear.

Dr. Bayley, in view of your testimony before the Senate about taking the more dangerous compounds off the market, when equally effective substitutes are available, would you subscribe to the idea that if there are significant safety advantages and less hazard in products that the labeling ought to tell the housewife just what she is facing and if there are advantages in a product in terms of safety that they should be allowed to get some distinction on there to let the housewife make an informed choice.

Dr. BAYLEY. I think Dr. Hays' statement is very excellent in this regard. We shouldn't in any case get ourselves in a position of saying that this is harmless when it is not harmless. We should be very careful here that, in the effort to increase the usage of the less-hazardous pesticides that we don't oversell them or give the housewife, or the user, any reason to believe that these are completely safe products. That is the position Dr. Hays is taking and I commend him for it.

Mr. NAUGHTON. I am only suggesting if there really is a safety advantage that the manufacturers of the less-dangerous product should be able to use that as a sales pitch in the hope that it will displace more dangerous products.

Dr. BAYLEY. But the whole point is we should use the very words you used yourself, "less dangerous," not "without danger."

Mr. NAUGHTON. I would go along with that.

Dr. IRVING. I think there is a point here I would like to make. Maybe this will restimulate further discussion. I hesitate to make it because of that, but let's hope it doesn't.

We are comparing the word "safety" and I think it is incorrect and misleading to do so. We register product A, and if it is used as directed, it is safe.

Product B, we register and used as directed; it too is safe. But they may be different products. Product A may be a chlorinated hydrocarbon and product B may be pyrethrum.

All we are trying to say is that you have a wider latitude for misuse of product B than of product A. Under the terms of registration, used as directed on the label, both products are safe and as used, one is no more safe than the other.

Mr. NAUGHTON. Is the Secretary fully informed on the arsenical situation?

Dr. BAYLEY. Yes, sir.

Mr. NAUGHTON. We would be happy to make a copy of the transcript available for his examination.

Mr. BAYLEY. I am sure he is informed on this.

Mr. NAUGHTON. We had some discussion at our previous hearing——

Mr. FOUNTAIN. Before you start, we have the Food and Drug representatives still over here.

Mr. NAUGHTON. We had some discussion at the last hearing with respect to certain possible conflict of interest questions involved in the appointment of Dr. Hansberry, a scientist with the Shell Chemical Corp. or one of its affiliates, to the task force headed by Dr. Hays in 1966. Now we find that there are minutes for only one of the meet-

ings of the task force. Is it customary not to keep minutes when you have an industry representative on such a task force?

Dr. IRVING. This task force was a group brought together to advise ARS on the operations of its Pesticides Regulation Division. The task force consisted of people from within the Department, some ARS, some not, and three people from outside the Department who were employed as consultants for the purpose of cooperating in this study and advise ARS with respect to its Pesticide Regulation Division. Under those circumstances we don't normally keep minutes.

Mr. NAUGHTON. Mr. Bucy, may I ask: I have been having some problem determining what the regulations are, but in order to avoid delaying the proceedings now, could you furnish for the record an analysis of the legal situation involved and your judgment or the judgment of the appropriate persons of the Department as to whether minutes should have been kept or should not have been kept in accordance with either regulations or policy of the Department?

Mr. BUCY. Surely.

(NOTE.—The subcommittee was subsequently advised by the Department of Agriculture that, in view of possible conflict-of-interest questions, the matter involving service of Dr. Hansberry on the task force is being referred to the Department of Justice. The subcommittee was further advised that a review of administrative policies and procedures involved will be made and a further report provided to the subcommittee at a later date.)

Mr. NAUGHTON. Minutes were kept for the first meeting. Mr. Alford, is it accurate that you kept those minutes?

Mr. ALFORD. Yes.

Mr. NAUGHTON. Why were you keeping minutes for the first meeting?

Mr. ALFORD. I was instructed to serve as secretary for that meeting.

Mr. NAUGHTON. Who appointed you to serve as secretary?

Mr. ALFORD. I received the first notice through a memorandum to the Division from the Deputy Administrator.

Mr. NAUGHTON. Was the appointment made by the Secretary?

Mr. ALFORD. It was announced along with the announcement of the appointment to the committee.

Mr. NAUGHTON. And that was announced by the Secretary's office?

Mr. ALFORD. I believe so.

Dr. IRVING. Yes, it was.

Mr. NAUGHTON. You were the executive secretary. And a part of your responsibility as such, as you interpreted it, was to keep minutes?

Mr. ALFORD. Yes.

Mr. NAUGHTON. Now, at the first meeting did you raise a question as to a possible conflict-of-interest question arising with respect to access to confidential information on the part of Dr. Hansberry?

Mr. ALFORD. I pointed out that there are restrictions in the law and that, since Dr. Hansberry was an industry man, that should be clearly understood.

Mr. NAUGHTON. What response did you get?

Mr. ALFORD. Well, I was assured that it was clearly understood, that Dr. Hansberry understood the restrictions of the law as well as everybody else.

Mr. NAUGHTON. Who assured you of that?

Mr. ALFORD. Dr. Hansberry, for one. Dr. Hansberry assured the group he did understand these restrictions in the law.

Mr. NAUGHTON. Was any order issued to your knowledge that specifically stated that Dr. Hansberry was not to have access to confidential information?

Mr. ALFORD. Not to my knowledge.

Mr. NAUGHTON. Was there to anyone else's knowledge?

Dr. HAYS. Yes, sir. I made it very clear in one of our meetings that this was as stated at the first meeting regarding the confidentiality of certain types of the material, and I expected every member of the committee to respect it.

Mr. NAUGHTON. Did you see that the employees who had custody of confidential information were so notified?

Dr. HAYS. I didn't notify the Division personally.

Mr. NAUGHTON. There is no written document reflecting the notice that was given?

Dr. HAYS. No, sir.

Mr. NAUGHTON. You kept minutes only for the first meeting. Why didn't you keep minutes for the subsequent meetings? There were some, weren't there?

Mr. ALFORD. At the second series of meetings, I was advised it wouldn't be necessary to serve as secretary.

Mr. NAUGHTON. Who advised you?

Mr. ALFORD. Dr. Hays, chairman of the committee.

Mr. NAUGHTON. The last thing that occurred according to the minutes of the first meeting was that you raised this question about access to confidential records by Dr. Hansberry. Thereafter, you were told that your services would no longer be required.

Mr. ALFORD. I was not told that at the time. I was told that at the beginning of the second series of meetings.

Mr. NAUGHTON. You came to the second series of meetings prepared to take notes?

Mr. ALFORD. Yes.

Mr. NAUGHTON. Dr. Hays told you in effect to go on back to whatever you had been doing before, that you were not wanted at the meeting?

Mr. ALFORD. He told me it wouldn't be necessary for me to attend the meeting.

Mr. NAUGHTON. Did you interpret that as leaving you any choice as to whether it was optional with you to stay or that you simply were not wanted?

Mr. ALFORD. Well, I wasn't needed.

No, I didn't interpret it as having any choice.

Mr. NAUGHTON. Did you make any comment to Dr. Hays as to the fact that no minutes might be kept if you were not there?

Mr. ALFORD. No.

Mr. NAUGHTON. Dr. Hays, why did you decide that Mr. Alford should not keep minutes of subsequent meetings?

Dr. HAYS. Mr. Chairman, Mr. Naughton, when we met for the first time and after having reviewed the charges to the committee to carry out its responsibilities in this review, it became immediately apparent that we would have to approach this entire problem a little differently than I presume many of the members thought we would. As chairman of the committee, I wanted to have free and open discussions. Mr. Al-

ford was a member of the Pesticides Regulation Division. He was intimately associated with the registration process. My request had no reflection whatsoever on Mr. Alford's integrity. It was done in good faith to try and create an atmosphere whereby all of us could review all of the aspects of the Division without any personal attack on Mr. Alford or anyone else. Therefore, it seemed to me that it would be better not to have a member of the Division at the discussions.

I assumed all responsibility for this. It was my request. I think it did create a better atmosphere for thorough discussions.

Dr. BAYLEY. It is important for the record here that Dr. Hays was not a member of the Department of Agriculture at that time.

Dr. IRVING. And also to supplement what Dr. Hays said, his action in relieving Mr. Alford of his responsibilities on the committee was concurred in by Dr. Anderson at that time.

Mr. NAUGHTON. Dr. Anderson, did you seek to make any alternative arrangements for minutes to be kept?

Dr. ANDERSON. No, sir.

In talking to Dr. Hays, he was of the opinion that the committee could operate effectively through notes being kept by the chairman and by the chairman of the subgroups that were established to function.

Mr. FOUNTAIN. Did you keep some notes?

Dr. HAYS. Yes, sir.

Mr. NAUGHTON. Who was responsible for clearing the appointment of Dr. Hansberry from a conflict-of-interest standpoint?

Dr. ANDERSON. Dr. Hansberry, like all other consultants to the Department, is required to fill out a conflict-of-interest form, form 68, it was reviewed by the personnel people of the Agricultural Research Service, forwarded to the Department personnel office and it is customary where they have raised a question to the propriety of the statement, they forward it to the Office of General Counsel for their evaluation.

Mr. NAUGHTON. Was it forwarded to the Office of General Counsel?

Mr. REID. We have no record that this particular case was forwarded to the Office of General Counsel or that there was any particular concern or question concerning it. At this time the financial interest form is not available so it is not possible for us to say what was contained on the form but neither the Office of the Secretary nor the Office of the General Counsel has a record that it was cleared specifically with the Office of General Counsel at that time.

Mr. NAUGHTON. I have a personnel form here apparently forwarded to your office by the Agricultural Research Service. It states that a standard form 68, statement of employment and financial interest, completed by Dr. Hansberry dated June 17, 1965, is attached. We have been unable to locate that document. The personnel form states that, "The Agricultural Research Service does not have or know of any official business with the persons, firms, or institutions with which Dr. Hansberry has other employment or financial interest as reported on the SF 68 which might constitute a conflict of interest." Now, how many products does the Shell Chemical Corp. or its affiliates have registered as pesticides?

Mr. ALFORD. They have well over 100. I would have to check the exact figure.

Mr. NAUGHTON. Is there anyone bigger than they are in this field, Mr. Alford?

Mr. ALFORD. Yes.

Mr. NAUGHTON. They are one of the largest?

Mr. ALFORD. They are a large company.

Mr. NAUGHTON. Who made the determination in the Agricultural Research Service that the fact that Shell had 100 products registered was not sufficient basis for not utilizing Dr. Hansberry's service on a task force designed to review the registration process?

Dr. IRVING. The situation, as I have since refreshed myself on this, Mr. Naughton, was that Dr. Hansberry's name came to our attention because he had served on a National Academy of Sciences committee on zero tolerance.

Mr. NAUGHTON. With Dr. Hays?

Dr. IRVING. Along with Dr. Hays. So that he was known from his performance on that committee as being a competent and objective individual and knowledgeable in this general area.

Dr. Hays suggested that Dr. Hansberry would be a good adjunct to this committee because of the factors I just mentioned. The principal reason for wanting a man of Dr. Hansberry's competence was to examine the procedures being used and the facilities and personnel that were applying them at the several laboratories of the Pesticides Regulation Division.

I think you will find the period in which he was actually employed and paid by the Agricultural Research Service was 7 days. He was hired, I think, as a consultant in about midyear 1965 and he went off the rolls in January 1966.

His form 68, the conflict-of-interest statement required, is destroyable 2 years after the employee leaves the service and we assume that that is what happened to the record——

Mr. NAUGHTON. Disposable. Whether that means destruction I am not certain yet.

Who approved his service from a conflict-of-interest standpoint?

Dr. IRVING. As Dr. Anderson indicated, the Agricultural Research Service. We among others, but principally our personnel division, has responsibility for looking at these conflict-of-interest statements. They had no reason to conclude there was any conflict of interest from the report on form 68. Neither did the office of personnel to which it was referred. So that I would suspect there was no indication of need for sending it to the Office of the General Counsel or to anyone else since there was nothing apparent in it.

Mr. NAUGHTON. Somebody made the statement that the Agricultural Research Services did not have or know of any official business of persons, firms or institutions with which Dr. Hansberry has other employment or financial interest as reported on his SF–68 which might constitute a conflict of interest. That is a conflict-of-interest clearance. Who put that on there? Somebody in the Agricultural Research Service apparently did it or else conveyed the information so it was put down in the personnel office.

Dr. IRVING. I don't know, but I would suspect it was our personnel division.

Mr. NAUGHTON. Can you ascertain who did it and let the subcommittee know?

Dr. IRVING. Yes; we can. The records are nonexistent, as has already been indicated, but—is there a signature on that form?

Mr. NAUGHTON. Max Reid's signature is on it.

Dr. IRVING. That is the Department Office of Personnel.

Mr. NAUGHTON. There was a prior clearance or recommendation for clearance in the Agricultural Research Service apparently.

Dr. IRVING. That would be normal practice; yes.

(Dr. Irving subsequently advised that he had been unable to find out who had cleared the Hansberry appointment from a conflict-of-interest standpoint on behalf of the Agricultural Research Service.)

Mr. NAUGHTON. Was a part of the rationale for approving this the fact that he was to work only on labs? Was it intended that he would be reviewing the criteria used in registrations, working in the area of registrations?

Dr. IRVING. I can't testify as to intent. I am just simply telling you what he did.

Mr. NAUGHTON. Are you sure that is what he did? What basis do you have for making that statement?

Dr. IRVING. I am assured by Dr. Hays that is what he did.

Mr. NAUGHTON. Let me read from the sole existing minutes for this task force—the one meeting for which minutes were kept. It states here "the following subcommittees were appointed and asked to study their particular areas as time would permit between now and the next meeting." The important one is No. 3, "subcommittee to review criteria used in evaluating applications." Listed in the membership of that committee is T. Roy Hansberry. It says nothing about reviewing labs. It says to review the criteria used in evaluating applications.

Dr. ANDERSON. In reviewing criteria, it does not mean that they would have access to confidential information. Criteria is the kinds of things rather than observing actual material that was furnished.

Mr. NAUGHTON. It doesn't suggest they are out seeing if the lab equipment is adequate either, does it?

Dr. ANDERSON. He had visited the labs on the west coast before coming in on this visit. He visited three of the labs, San Francisco, New York, and I believe Denver.

Mr. NAUGHTON. To conclude this, Mr. Bucy, in connection with the submission you will make on this, would you indicate whether or not the Department feels there was any departure from established procedures or desirable procedures in connection with what happened in this case and whether or not it would be likely the same type of thing would happen in the future?

Mr. BUCY. Yes.

(The subcommittee was subsequently advised that, in view of possible conflict-of-interest questions, the matter is being referred to the Department of Justice. The subcommittee was further advised that a review of the administrative procedures and actions involved will be made by the Office of the Inspector General. A copy of current USDA rules and regulations relating to employee responsibilities and conduct was also provided and is in the subcommittee files.)

Mr. FOUNTAIN. Doctor, before we let you go and start with the representatives of the Food and Drug Administration, has your branch

ever appeared before a congressional committee in connection with this problem before, that you know of?

Dr. IRVING. I have no recollection of our appearing before another committee in connection with this problem.

Dr. ANDERSON. You mean the problem under discussion today? No, sir.

Mr. FOUNTAIN. Any questions?

Mrs. DWYER. No questions.

Mr. MYERS. I have one question. Dr. Hays, in testimony before the subcommittee on May 7, there was much discussion you might recall, about thallium products and at that time it was established for the record that thallium registrations were canceled in August 1965.

There were questions involving whether or not there was ever a recall action on thallium, whether or not warning to the public was issued subsequent to August 1965.

I recall the answer to both of those was "No" at that time.

Has either action been taken since May 7, when we discussed this last?

Dr. HAYS. There has been no recall action. As to whether there has been any other notice than what I indicated in the original hearing, it seems to me that in the information to be sent up to you—am I correct, Mr. Alford, that there was a notice sent out in regard to thallium?

Mr. ALFORD. To the inspectors?

Dr. HAYS. At the time of cancellation.

Mr. ALFORD. Yes, to the registrants.

Dr. HAYS. I meant public information. Press releases.

Mr. ALFORD. I believe there was a press release, yes.

Dr. HAYS. The reason I ask is that I may be in error on that statement there had been no press releases. I think, in checking the records since the hearing, that we did send you some information regarding the press release.

Mr. MYERS. That was the 1965 press release, was it not?

Dr. HAYS. Yes, Mr. Myers.

Mr. MYERS. The line of questioning in testimony of May 7 had to do with the fact that thallium products were being found in 1968?

Dr. HAYS. Yes, sir.

Mr. MYERS. The press release that was discussed at that time was a warning to the public that the products apparently still are around and still being purchased and available for sale.

So, once again, has a press release been issued to warn the public of this situation since then?

Dr. HAYS. There has been no press release, but we have instructed our inspectors to make a very careful survey in every part of the country in which they travel to make a special effort to determine if any thallium is in the channels of trade.

Mr. MYERS. I would like to establish for the record in this connection that our review of the IBM runs at the Poison Control Center for a 10-month period beginning January 1968 through October 1968—that was the most recent available run they had in early June of this year—showed 20 thallium poisonings in the first 10 months of 1968.

So, in addition to informing your inspectors, it might well be a good idea, particularly in view of the discussion on May 7, to reconsider the need for a warning to the public.

Dr. BAYLEY. Mr. Chairman, with your permission, I would like to make a comment at the conclusion of this. As I mentioned earlier, I came into this a few months ago, and have been reviewing the situation. I believe that the record does show that since 1966 and since Dr. Hays' appointment as Director, there has been progress in improving the administration of FIFRA.

Nevertheless, it is obvious from my information, including the GAO report and the two hearings I have attended here, that there is a real need to accelerate this progress.

What I want to tell you is that I will pledge to you that I and the Administrator of ARS will personally direct our attention to bring all the resources of the Department to the assistance of the Pesticides Regulatory Division in order to get this progress accelerated.

This applies not only to the matter of activities within the Department itself, but our interdepartmental actions, involving other departments of the Government.

Mr. FOUNTAIN. Thank you very much.

Dr. IRVING. At the risk of saying "Me too," I made almost identical notes and would have said this if Dr. Bayley hadn't said it.

Mr. FOUNTAIN. We would like to make as many Christians as we can. [Laughter.]

Thank you very much for coming up.

Mr. Goodrich, would you and your associates come up?

We have Mr. Duggan, Deputy Associate Commissioner for Compliance and Dr. Harris, Chief of the Division of the Pesticide Registration and Mr. William Goodrich, almost an institution over here, Assistant General Counsel to Food and Drugs and Environmental Health Division.

We are delighted to have you here.

I believe you have a statement, Mr. Duggan.

In the interest of time, if you will, we would appreciate your summarizing it. We will put the full statement in the record.

STATEMENT OF REO E. DUGGAN, DEPUTY ASSOCIATE COMMISSIONER FOR COMPLIANCE; ACCOMPANIED BY DR. T. H. HARRIS, CHIEF, DIVISION OF PESTICIDE REGISTRATION; AND WILLIAM W. GOODRICH, ASSISTANT GENERAL COUNSEL, FOOD, DRUGS, AND DEVELOPMENTAL HEALTH DIVISION

Mr. DUGGAN. Thank you, Mr. Chairman.

We will attempt to summarize the material we have.

As you know, the President's Science Advisory Committee in 1963 recognized there was a need for greater coordination between the various agencies concerned with pesticides and in its report recommended that the three Departments, Agriculture, Interior, and Health, Education, and Welfare, review and define their respective roles and also recommended that the health functions relating to pesticides be vested in HEW.

As a result of this, a memorandum agreement between the Departments was entered into in 1964 in order to effectively coordinate the functions of the three Departments. The Public Health Service of the Department of Health, Education, and Welfare was assigned a responsibility to review labels submitted to the Department of Agricul-

ture and advise the USDA on health aspects associated with the use of pesticide chemicals such as warnings against undue exposure to the population, especially in household applications and to fieldworkers.

The Food and Drug Administration, of course, continued the review of intended uses which might result in food contamination and the establishment of safe tolerances. The agreement in general, calls for exchange of information between the three Departments on the uses of pesticides. Specifically, it requires the USDA to furnish the other two Departments on a weekly basis a list of all proposals affecting registration and requires HEW to furnish a weekly listing on all proposals affecting tolerances.

Procedures and time limitations were specified for the lodged objections. When objections are lodged, 2 weeks are provided for departmental representatives to reach agreement. If this fails, the matter is to be referred to the Secretary of the Department responsible for the final action in the situation and he is then responsible for making the final determination.

The other Departments are also to receive advance notice of such final determination. Those parts of the agreement affecting FDA were followed satisfactorily.

In July 1968, the function of reviewing such labels for matters related to health were transferred to the FDA from the Communicable Disease Center of the Public Health Service. After the assignment of this responsibility to FDA, a task force was established to determine the most effective location of this program within FDA.

The conclusion was reached that the registration unit should be within the Office of Product Safety recommended for establishment in the Bureau of Medicine. This placement enables the unit to readily utilize the medical expertise in that Bureau.

Since December of 1968 when the Division of Pesticide Registration formally became an operating unit, we have been reviewing the adequacy of the memorandum of agreement. After the transfer of the label registration function to FDA, it was determined that the prevailing philosophy had been that the PHS label review was purely an advisory procedure and no formal checks were made to determine whether the recommendations were heeded.

Since there had been no formal system established to insure that the recommendations on the health aspects of label registration were being accepted by USDA, in late January discussions were initiated to hold a meeting of the Department representatives as set forth in the memorandum of agreement. This meeting was held on March 19, 1969.

Among the topics discussed were operational problems associated with the agreement and the need to revise and update the agreement. Among the decisions reached at the meeting was the establishment of a monthly meeting of agency representatives to resolve differences that may have arisen. This was to be carried on for several months prior to undertaking a revision of the agreement.

USDA memorandum of June 17, 1969, notified FDA of the first such meeting to be held on June 25. In February, FDA had suggested to USDA that a monthly meeting might be valuable in meeting the objectives of the agreement.

Also in February, FDA wrote to USDA concerning the quarterly reports and suggested that there be a category reflecting the actions

taken on the objections raised by the Department. No response has been received.

There were two additional problems discussed at the March meeting.

Mr. FOUNTAIN. Is that February of this year?

Mr. DUGGAN. Yes, February of 1969.

The first of the additional problems discussed at the March 19 meeting was the need for FDA to review the final printed labels where recommendations for change had been made, and second, the need for a clearer definition of the firm scientific evidence required by USDA to support another Department's objection.

FDA believes that the lack of scientific evidence is sometimes as important for consideration as positive evidence. The Division of Pesticide Registration reviews about 300 pesticide labels and evaluates toxicological data that are submitted for registration each week. Their comments on the adequacy of the labeling and data are furnished the Pesticide Registration Division in a weekly letter.

The objections are forwarded to the Department of Agriculture in this weekly letter. During the period July 1, 1968, to June 1, 1969, FDA filed 177 objections to registrations. However, we do not know how many pesticide labels the Department of Agriculture has registered over the objections.

The primary responsibility for obtaining the proof of safety on residue tolerances which are established under procedures discussed in the more detailed statement is placed on the industry or on the firm promoting the use of the pesticide chemicals.

FDA is responsible for the scientific judgment concerning the safety of the tolerances.

In arriving at a decision that the proposal is safe, our scientists use all available information in addition to that supplied in support of the tolerance.

As of July 1, 1968, there were 3,115 tolerances or exemptions established on 175 pesticide chemicals. After the tolerances have been set, there are surveillance activities to determine compliance with tolerances and sanctioned uses which includes inspectional investigations in the growing fields and the analysis of preharvest and postharvest samples.

There are information and educational activities to keep the grower knowledgeable of our findings, be they good or bad. This assists the grower in avoiding shipment of foods with illegal residues.

There are also control activities to remove hazardous foods from consumption channels through State and Federal legal actions.

Finally, there are the total diet investigations which we use as an index to the dietary intake of pesticide residues.

During the period of July 1, 1967, to June 30, 1968, the Food and Drug Administration examined approximately 18,000 samples of foodstuffs, both domestic and imported, resulting in 17 seizures. In addition, this is not in the statement, there were 29 detentions of imported foods.

The vast majority of the samples examined contained no pesticide residues or residues which were below the tolerance set under the procedures provided for in the act.

I have a listing of the seizures accomplished by FDA since 1965. The total diet study which can be characterized as the final check on

the tolerance system have shown, throughout 4 years of study, that the dietary intake of pesticide chemicals is well below the acceptable daily intake established by the food and agricultural organizations in the World Health Organization expert committees and below those intake levels anticipated by our scientists when considering proposals for tolerance.

(NOTE.—The list of seizures referred to by Mr. Duggan is in the subcommittee files.)

Mr. Chairman, the staff requested we discuss our activities relating to vapona, a chemical used to control such pests as fruit flies.

In reviewing the labeling for vapona insecticide resin strips, in accord with the interdepartmental agreement in 1965 HEW objected to the registration because of concern about the long continuous exposure of individuals to vapors of DDVP and especially the use in houses where infants are exposed and in hospitals where ill and debilitated patients are housed.

In 1967 following discussions with USDA representatives and representatives of the sponsor, the PHS decided to withdraw its objection provided the label bear the statement, "Do not use in rooms continuously occupied by infants or infirm individuals."

Vapona is also the subject of four regulations promulgated by FDA for use in or on foods. These tolerances were established on safety data from feeding studies on laboratory animals over extended periods of time. Judgments were made on the same basis as it used in setting other tolerances for food. We believe the food tolerances are sound. There is possible risk in translating the results from animal feeding studies to probable effect of inhaled poison. Inhalation is not comparable to oral ingestion. When you eat poisons, there are protective mechanisms. They may be destroyed or not absorbed in the gut or detoxified in the liver. Poisons inhaled in the lungs go directly into the bloodstream, thus escaping those protective mechanisms.

Whether the original objection to registration of vapona strips in 1965 should have been withdrawn in 1967 is a matter that the Commissioner's office has decided must be reviewed. The review will cover its use in any places. The review will be completed and a decision reached by July 31, 1969.

Your staff has asked specifically what we plan to do about the residues of vapona that may result in food when the insecticide is exposed in kitchens or dining rooms. The probable residues are relatively small; thus we plan to await the results of the review that is to be completed by the end of July. If this should result in a recommendation to the Department of Agriculture that registration be withdrawn, and if registration is withdrawn, that would take care of the matter. If there is some other result, we will consider the matter at that time and report back to this committee.

Mr. Chairman, this concludes the summary of the material.

We will be happy to attempt to answer any questions you or the committee or the staff might have.

(The statement follows:)

PREPARED STATEMENT OF REO E. DUGGAN, DEPUTY ASSOCIATE COMMISSIONER FOR COMPLIANCE, FOOD AND DRUG ADMINISTRATION, CONSUMER PROTECTION AND ENVIRONMENTAL HEALTH SERVICE, PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Thank you, Mr. Chairman, for this opportunity to discuss certain activities of the Department of Health, Education, and Welfare relating to or affecting the regulation of pesticides.

Regulation of the use of pesticides in our society is a diverse function and is carried out by several agencies. The responsibility for registration of pesticides and pest control materials has been placed in the U.S. Department of Agriculture. These products may not be legally shipped in interstate commerce without prior registration. When the proposed use of a pesticide will result in residues on a feed or food crop, the registration by USDA is not granted until a tolerance has been established by the FDA. The Federal Insecticide, Fungicide, and Rodenticide Act requires that before registration and shipment in interstate commerce, the pesticide must be shown to be safe when used as directed and effective for the purpose claimed on the label. The Federal Food, Drug, and Cosmetic Act, under the pesticide chemical amendments and food additive amendments, requires that when the registered uses result in residues on or in food and foodstuffs, a safe tolerance be established.

The Interior Department has programs designed to protect the fish and wildlife from pesticidal contamination; the Department of Transportation regulates shipment of pesticides by interstate carriers; and the Department of Defense has several programs involving the use and/or control of pesticides.

The President's Science Advisory Committee in 1963 recognized that there was a need for greater coordination between these various agencies and in its report recommended that the Secretaries of Agriculture, Interior, and Health, Education, and Welfare review and define their respective roles and also recommended that health functions relating to pesticides be vested in HEW. Pursuant to this report and its recommendations, a memorandum of agreement between the Department of Agriculture, the Department of the Interior, and the Department of Health, Education, and Welfare was entered into in 1964 in order to effectively coordinate the functions of the three Departments. The Public Health Service of this Department, in accord with the agreement, was assigned the responsibility to review labels submitted to the Department of Agriculture and advise the USDA on health aspects associated with the use of pesticide chemicals such as warnings against undue exposure to the population, especially in household applications and to fieldworkers. The FDA, of course, continued the review of intended uses which might result in food contamination and the establishment of safe tolerances.

The agreement in general calls for exchange of information between the three Departments on uses of pesticides. Specifically, it requires USDA to furnish to the other two Departments, on a weekly basis, a listing of all proposals affecting registration and requires HEW to furnish a weekly listing of all proposals affecting tolerances. Procedures and time limitations were specified for the lodging of objections. When objections are lodged, 2 weeks are provided for departmental representatives to reach agreement. If this fails, the matter is referred to the Secretary of the Department responsible for final action in the situation and he is then responsible for making the final determination. The other Departments are also to receive advance notification of such final determination.

Those parts of the agreement affecting FDA were followed satisfactorily.

In July 1968, the function of reviewing such labels for matters related to health as well as other health related activities was transferred to the FDA from the Communicable Disease Center of the Public Health Service.

After the assignment of this responsibility to FDA, a task force was established to determine the most effective location of this program (and others) within FDA. The conclusion was reached that the registration unit should be within the Office of Product Safety recommended for establishment in our Bureau of Medicine. This placement enables the unit to readily utilize the medical expertise in that Bureau. Since December of 1968 when the Division of Pesticide Registration formally became an operating unit, we have been reviewing the adequacy of the memorandum of agreement.

After the transfer of the label registration function to FDA, it was determined that the prevailing philosophy had been that the PHS label review was a purely advisory procedure and no formal checks were made to determine whether the recommendations were heeded.

Since there had been no formal system established to insure that the recommendations on the health aspects of label registration were being accepted by USDA, in late January discussions were initiated to hold a meeting of the Department representatives as set forth in the memorandum of agreement. This meeting was held on March 19, 1969. Among the topics discussed were operational problems associated with the agreement and the need to revise and update the agreement. Among the decisions reached at the meeting was the establishment of a monthly meeting of the agency representatives to resolve differences that may have arisen, prior to undertaking a revision of the agreement. USDA's memorandum of June 17, 1969, notified FDA of the first such meeting to be held on June 25th.

In this connection, in February FDA had suggested to USDA that a monthly meeting might be valuable in meeting the objectives of the memorandum of agreement. Also, in February FDA wrote to USDA concerning the quarterly reports and suggested that there be included a category reflecting the actions taken on the objections raised. No response has been received.

Two additional problems discussed at the March 19 meeting were, first the need for the FDA to review final printed labels where recommendations had been made and second the need for a clearer definition of the firm scientific evidence required by the USDA to support another Department's rejection. FDA believes that the lack of scientific evidence is sometimes as important for consideration as positive evidence.

To illustrate the magnitude of this problem, FDA's Division of Pesticide Registration reviews each week up to 300 pesticide labels and evaluates toxicological data that are submitted for registration or reregistration under the Federal Insecticide, Fungicide, and Rodenticide Act administered by USDA. Their comments on the adequacy of the labeling and data are furnished the Pesticides Regulations Division, Agricultural Research Service, USDA, in a weekly letter.

Objections are forwarded to the Department of Agriculture in our weekly letter. FDA has during the period July 1, 1968 to June 1, 1969, filed 177 objections to registrations.

However, we do not know how many pesticide labels the Department of Agriculture has registered over HEW's objections. The steps we have taken as discussed above, are designed to obtain information of this nature in order to more fully meet our responsibilities. In addition, this entire operation of reviewing pesticide labels is being reviewed within FDA.

Mr. Chairman, at this point I would like to discuss, as you requested, the legal framework under which we regulate the use of pesticides in or on foods.

Chemicals added to foods are regulated by FDA through preclearance procedures and the authority to establish and enforce safe legal limits for such additives. Basically, the regulatory scheme is accomplished through several amendments to the Food and Drug Act—the pesticide chemicals amendment, the food additives amendment, and the color additives amendment although other provisions of the act, such as section 406 serve as part of the system designed to keep our food supply safe.

Under the Pesticide Chemicals Amendment of 1954, economic poisons which are not generally recognized as safe by qualified experts, may not be present in or on raw agricultural commodities unless a safe tolerance (which may even be zero) has been established. Of course, residues in excess of the tolerance would also render the product adulterated. Such tolerances are established only after the USDA has certified that the pesticide chemical is useful to agriculture when employed as proposed in the petition. Exemptions from the requirement of a tolerance are also authorized if not inconsistent with the public health. Raw agricultural products are defined to include all foods in their raw or natural state.

Food additives, pursuant to the food additives amendment, also must be used in accord with legally established use levels. In addition to being safe, they must not be used in amounts higher than necessary to accomplish the intended physical or technical effect desired. This category basically includes any substance whose intended use will become or reasonably result in its becoming a part of a food or affecting the characteristics of the food, except for those articles which are again generally recognized as safe by qualified experts. Pesticide chemicals used in or on raw agricultural products are, however, specifically excluded from the food additive provisions of the act. Pesticides in processed foods are, however, subject to regulation under this amendment.

The food additives amendment contemplates intentional addition of such substances to food including food for animals. Section 406 of the act covers the

addition of any poisonous or deleterious substance required or unavoidable in good manufacturing practices. When unavoidable, the Secretary is authorized to promulgate regulations limiting the quantity thus acceptable; however, no regulations permitting such uses have been issued under this provision. Thus, this section is employed when products (other than pesticides on raw agricultural products) have been accidentally contaminated during holding or shipment.

The primary responsibility for obtaining proof of safety of residue tolerances is placed on the industry or firm promoting the use of pesticide chemicals. The FDA is responsible for the scientific judgment concerning the safety of the tolerance. In arriving at a decision that the proposal is safe, our scientists use all available information, in addition to that supplied in support of the tolerance. As of July 1, 1968, there were 3,115 tolerances or exemptions established on 175 pesticide chemicals.

After the tolerance has been set, there are surveillance activities to determine compliance with tolerances and sanctioned uses which includes inspectional investigations in the growing fields and the analysis of preharvest and postharvest samples. There are information and educational activities to keep the grower knowledgeable of our findings, good and bad. This assists the grower in avoiding shipment of foods with illegal residues. There are control activities to remove hazardous foods from consumption channels through State and Federal legal actions. There are the total diet investigations which we use as an index to the dietary intake of pesticide residues.

For example, in surveillance and control activities, the Food and Drug Administration monitors pesticide usage and examines samples of raw agricultural commodities for pesticide residues. Any product found to contain an illegal residue would be subject to seizure, and the persons responsible for shipping foods in interstate commerce containing such residues are liable to prosecution. During the period of July 1, 1967, to June 30, 1968, the Food and Drug Administration examined approximately 18,000 samples of foodstuffs, both domestic and imported, resulting in 17 seizures. The vast majority of the samples examined contained no pesticide residues or residues which were below the tolerance set under the procedures provided for in the act.

These total diet studies, which can be characterized as the final check on the tolerance system, have shown, throughout the 4 years of the study, that the dietary intake of pesticide chemicals is below the acceptable daily intake established by the FAO/WHO Expert Committee, and below those intake levels anticipated by our scientists when considering proposals for tolerance.

Mr. Chairman, you also requested us to discuss our activities relating to vapona (DDVP), a chemical used to control such pests as fruit flies. In reviewing the labeling for vapona insecticide resin strips, in accord with the interdepartmental agreement, HEW, in 1965, objected to the registration because of concern about the long, continuous exposure of individuals to vapors of DDVP and especially the use in houses where infants are exposed and in hospitals where ill and debilitated patients are housed. In 1967, following discussions with USDA representatives and representatives of the sponsor, the PHS decided to withdraw its objection provided the label bear the statement, "Do not use in rooms continuously occupied by infants or infirm individuals."

Vapona is also the subject of four regulations promulgated by FDA for use in or on foods. These tolerances were established on safety data from feeding studies on laboratory animals over extended periods of time. Judgments were made on the same basis as is used in setting other tolerances for food. We believe the food tolerances are sound.

There is possible risk in translating the results from animal feeding studies to probable effect on inhaled poison. Inhalation is not comparable to oral ingestion. When you eat poisons, there are protective mechanisms. They may be destroyed or not absorbed in the gut or detoxified in the liver. Poisons inhaled in the lungs go directly into the bloodstream, thus escaping those protective mechanisms.

Whether the original objection to registration of vapona strips in 1964 should have been withdrawn in 1967 is a matter that the Commissioner's Office has decided must be reviewed. The review will cover its use in any places. The review will be completed and a decision reached by July 31, 1969.

Your staff has asked specifically what we plan to do about the residues of vapona that may result in food when the insecticide is exposed in kitchens or dining rooms. The probable residues are relatively small, thus we plan to await the results of the review that is to be completed by the end of July. If this should result in a recommendation to the Department of Agriculture that regis-

tration be withdrawn, and if registration is withdrawn, that would take care of the matter. If there is some other result, we will consider the matter at that time and report back to this committee.

Mr. Chairman, this concludes my statement, and I would be happy to attempt to answer any questions you might have.

Mr. FOUNTAIN. Thank you very much, Mr. Duggan. Dr. Harris, I wonder if you would describe for us some of the types of uses which you have objected to unsuccessfully, which you regard to be the most serious.

Dr. HARRIS. We can divide this into five or six categories. The first category are products that are considered to be extremely hazardous when used and stored around the home.

The second category are products which are intended for use in treating seeds which are toxic and don't have a dye so that the treated seeds can be distinguished from human foods.

Another category is the use of human foods as baits in rodenticides around the home, phosphorous baits, for example, smeared on a slice of bread. Fruits used as baits.

Another category are products which have been shown to produce cancer in experimental animals that are still used and available for use around the home.

Another category are those products where we consider that the data are inadequate.

In other words, we object to registration until additional data are supplied.

I believe those are the main categories. We have compiled a list of objections for the past year, and we supplied your committee with a complete list of objections and indicated those objections which have since been withdrawn because of agreement reached with Agriculture.

Mr. FOUNTAIN. Those objections, if they haven't already been made a part of the record, will be made part of the record now.

I understand those objections constitute a thick book, so I think we should include in the record only some summarized objections for a shorter period provided by ARS. After the record is made, you may want to check it to see if you have any additions to make.

Mr. DUGGAN. We would like to do that.

Mr. NAUGHTON. If you like, we will submit the summaries submitted to us by ARS to FDA for examination and any comment you might want to add or any additions that you might want to make to it, and that can then go in the record.

(The comments made appear in the appendix on p. 301.)

Mr. FOUNTAIN. How long have you been having these monthly meetings of agency representatives?

Mr. DUGGAN. The first one is scheduled for tomorrow. [Laughter.]

Mr. FOUNTAIN. In other words, you haven't had any before?

Mr. DUGGAN. There have not been any before. It was thought this would be the best approach to pinpointing some of the major issues and problems before undertaking a revision of the agreement.

Mr. FOUNTAIN. Did you decide to have these conferences as a result of discussions between you and ARS?

Mr. DUGGAN. Yes, sir. This decision was made at the March 17 meeting of the departmental representatives under the memorandum of agreement—excuse me—March 19.

Mr. FOUNTAIN. Was the idea initiated by either agency, or was this conclusion reached after consultation between both of you?

Mr. DUGGAN. The idea initiated from the Food and Drug Administration in February, and was—Dr. Harris, I think made this request of the Department of Agriculture in a memorandum in February.

Mr. FOUNTAIN. We have you down here as Dr. Harris.

Dr. HARRIS. Either one is all right. I believe that the first one—the first contact was made by Dr. Worf over in CPEHS. I believe that you—Mr. Duggan—were asked to draw up an agenda for this March 19 meeting and then Mr. Kirk sent a memorandum over there designating the representatives for Food and Drug, and then we proceeded to have the meeting.

Mr. DUGGAN. Yes, but the question was directed to who initiated the monthly meeting.

Dr. HARRIS. FDA.

Mr. FOUNTAIN. How long have you been filing objections?

Dr. HARRIS. Since the agreement, beginning in 1964.

Mr. FOUNTAIN. Did you feel a need for these monthly meetings before you initiated this action?

Dr. HARRIS. Yes.

Mr. FOUNTAIN. Why hadn't you initiated it earlier?

Dr. HARRIS. I brought up the question at a meeting which Dr. Simmons and I had with USDA in Dr. Anderson's office in 1967. At that time the comment was that we don't seem to need to have meetings just for the sake of having meetings.

I pointed out the agreement called for an annual meeting, and we hadn't had any annual meetings. So that was the first time that I brought up the question of having a meeting.

Mr. FOUNTAIN. That was when?

Dr. HARRIS. 1967.

Mr. FOUNTAIN. The agreement was executed in 1964?

Dr. HARRIS. Yes.

Mr. FOUNTAIN. You had no meetings——

Dr. HARRIS. We had no meetings as far as I know, since the beginning of the agreement, although the agreement calls for an annual meeting.

Mr. FOUNTAIN. Under the agreement who was supposed to initiate the meeting?

Dr. HARRIS. I dont' believe any one agency, according to the agreement—the agreement just states there will be an annual meeting.

Mr. FOUNTAIN. It looks like there might have been a defect in the agreement, doesn't it? There should be some understanding as to who would initiate it. Too often, especially where different agencies are involved, I can see how one may wait for the other to initiate the action.

Now, I believe you said FDA suggested to USDA that the monthly meeting might be valuable in meeting the objectives of the memorandum of agreement. You have been talking about that.

Then in February you say, Mr. Duggan, you wrote the Department of Agriculture concerning the quarterly reports and suggested that there be included a category reflecting actions taken on objections raised.

You said no response has been received.

Mr. DUGGAN. Yes, sir.

Mr. FOUNTAIN. You mean you received no response at all?

Mr. DUGGAN. None at all.

Mr. FOUNTAIN. No telephone call?

Mr. DUGGAN. No phone calls, no letters.

Mr. FOUNTAIN. Sounds like a Congressman who doesn't want to get reelected.

[Laughter.]

Well, did you pick up a phone and call and talk to anybody in the ARS?

Dr. HARRIS. I did talk with Dr. Hays following those two communications and he told me they were planning to have these meetings, but hadn't gotten around to setting a date.

Mr. MYERS. Quarterly reports, I believe.

Dr. HARRIS. Well, we had no reply from my letter to Dr. Hays suggesting we have a monthly meeting. We had no reply from Mr. Kirk's letter to Dr. Anderson raising the question about a category for objections in the quarterly report. We have since received a letter from Dr. Hays regarding a meeting tomorrow.

Mr. FOUNTAIN. You made what to me is a meaningful statement when you said two additional problems discussed at the March 19 meeting were, first, the need for FDA to review final printed labels where recommendations had been made, and second, the need for clearer definitions of the firm, scientific evidence required by USDA to support another Department's rejection.

Then you say FDA believes that the lack of scientific evidence is sometimes as important for consideration as positive evidence.

I agree with that, but I think it would be good if you would elaborate somewhat for the record.

Mr. DUGGAN. Would you like to elaborate on that?

Dr. HARRIS. Yes. Shall we take up the matter of the scientific evidence? The agreement requires that the Department raising a question about the registration, furnishing scientific evidence to support this question, objection, what have you—we discussed that at our March 19 meeting, and we have taken a position all along that it's not our responsibility to provide scientific evidence to support an objection.

On the other hand, it is a responsibility of the registrant to provide all the information establishing the safety of a product.

We took the position, also, that the lack of scientific evidence is reason enough to express some concern about the registration, continued registration of a product.

We review, in most cases, proposed labeling. These labels are sometimes in the form of typewritten drafts. We don't see the final, approved label.

We don't see the final, printed label.

We have asked FDA if we could obtain copies of the final, printed labels which reflect not only our comments but also those of the Department of Agriculture.

This question was discussed at our March 19 meeting, and I don't believe the question was fully resolved.

There is a statement in Dr. Hays' report that they are looking into the matter, but presumably we will get copies when they are available. But there is not really a positive statement to that effect.

Mr. FOUNTAIN. I know this agreement is between HEW, Agriculture, and the Department of the Interior. Was it anticipated all three of the Departments would meet?

Dr. HARRIS. Right.

Mr. FOUNTAIN. Is Interior scheduled to meet with you at your first meeting?

Dr. HARRIS. Yes.

Mr. FOUNTAIN. Section 2(d) of the agreement reads as follows:

> If one Department concludes that the proposal should be rejected in whole or in part, this view shall be expressed in writing and shall be supported by appropriate scientific evidence. Upon being notified, the Department responsible for final action will take the initiative to work out a basis for agreement.

This would indicate when you submit an objection you would support it with appropriate scientific evidence. Is that what you do?

Mr. DUGGAN. As a matter of fact, objections are not supportable in terms of scientific evidence, per se, on safety. It's the conditions behind which the product is being used or distributed.

Mr. FOUNTAIN. And common knowledge of the nature of the article.

Mr. DUGGAN. Place some of the substances in any household where a child can get hold of them, and they do get them, we believe there is no need for—what kind of scientific evidence can you give to support that sort of position?

Mr. FOUNTAIN. I guess that's what you had in mind when you said lack of scientific evidence is sometimes as valuable as evidence.

Mr. GOODRICH. Also, they were raising some very basic policy questions about the nature of poisons that should be allowed for registration for use around the home. Some were pesticides with a very high level of dialdrin, which is a highly toxic substance. Other objections were to rat poisons, sodium fluoride and sodiumfluorosilicate, well known to be highly toxic, and what Dr. Harris was objecting to was registration of any such product that will place in the home a container which the consumption of a very small amount of which might well result in fatality.

He was raising with USDA some basic issues of the sort you have been exploring with them in the arsenic situation. Should you allow a highly toxic rodenticide like sodiumfluorosilicate or sodium fluoride in these concentrations around the home? That was the nature of the most serious objections that PHS was presenting.

When Mr. Kirk met with USDA in March, the issue was made that some of the objections were of this nature and the type of evidence that would be needed to support the objection should be turned around. That is, we should explore what evidence there is to prove safety. This is the nature of the problem: That we as a Department saw a need for a great deal of clarification between us and USDA.

Food and Drug, as you know, acquired this activity from PHS as a result of the reorganization last July, and Dr. Harris' group became a part of Food and Drug effectively in December, and so a review was undertaken to examine some of the objections and what was being done about them. We, as a regulatory agency, took a little bit differ-

ent view than PHS as a research agency did and inquired about what happened to these objections.

This leads us to request the final, printed labeling and regular meetings with the Agriculture Department so that the differences over these policy issues could either be found inadequate or ironed out.

Mr. FOUNTAIN. That's our objective in moving forward with the program now. What responses did you usually get to these objections?

Dr. HARRIS. We received no response to our letters. We state in each weekly letter we will be glad to discuss these questions at any time with you, but we almost invariably have no reply. I undertook to make an inquiry once about the number of labels that are registered, and we have no reply to that letter.

(The following letter and memorandum relating to a request for information concerning registration of certain pesticides products was subsequently obtained by the subcommittee:)

MARCH 21, 1969.

HENRY SHAW BUSSEY,
Entomologist, Pesticides Regulation Division, Agricultural Research Service, U.S. Department of Agriculture, Washington, D.C.

DEAR MR. BUSSEY: This is to confirm Mr. David Johnson's telephone request of March 20, 1969, requesting the following information:

1. Do any of the rodenticides currently registered bear directions calling for the utilization of human foods such as bread, apple slices, cheese, lettuce leaves, cookies, or colored peanuts for bait?

2. Are there any products currently registered containing aramite, aminotriazole or propionic anhydride?

3. What are the highest percentages of the following compounds registered for use in the home, on the lawn, or on home gardens:

(*a*) aldrin
(*b*) dialdrin
(*c*) toxophene
(*d*) methyl trithion
(*e*) lead arsenate
(*f*) lead acetate
(*g*) arsenic oxide
(*h*) heptachlor

4. Are there any registered uses for pentachlorophenol or arsenic acid on clothing?

5. Are there any products registered for seed treatment which do not contain a dye as part of their formulation as sold?

6. (*a*) Are any products containing alkyl mercury compounds registered? If so, what are there registered uses and concentrations?

(*b*) What is the highest percentage of phenylmercuric compounds allowed in a product which may be used in or around the home?

Thank you for your cooperation.

Sincerely,

THOMAS H. HARRIS, Ph. D.,
Director, Division of Pesticide Registration, Office of Product Safety, Bureau of Medicine.

MEMORANDUM OF TELEPHONE CONVERSATION OF APRIL 2, 1969, WITH DR. HARRY W. HAYS, DIRECTOR, PESTICIDES REGULATION DIVISION, U.S. DEPARTMENT OF AGRICULTURE

In order to obtain documentation for our contention that the U.S. Department of Agriculture disregards our recommendations on registration of certain products of questionable safety, the attached letter to Mr. Bussey was written. There was no other source of this information.

No reply to this letter was received as of April 2, 1969 so I called Mr. Harold Alford to ascertain whether or not this information would be forthcoming. I was told by Mr. Alford that Dr. Hays wanted to talk with me about our request and that he would call me. The following is a record of my conversation with Dr.

Hays: Dr. Hays said, first of all, that he wasn't sure he could furnish us with this information and asked why we wanted it. I explained that we were asked to document our claim that certain products were registered over the objection of the Department of Health, Education, and Welfare because of questions of safety. I told Dr. Hays that each question in our letter to Mr. Bussey involved use patterns to which we had objected and that although we were of the opinion that the use patterns were still registered we could not be certain unless we received such information from PRD.

Dr. Hays said that the information requested was, in his opinion, not related in any way to the requirements in the agreement and that the agreement did not require that PRD furnish us with such information. I reminded Dr. Hays that paragraph 1, Information, page 2 of the agreement states in part, "Upon request, the Departments of Agriculture and Health, Education, and Welfare, respectively, will furnish to the other Departments full information about any pending action on registration or the setting of a tolerance." To this he did not comment.

Dr. Hays told me that as a result of the two General Accounting Office reports he was suspicious of everybody and that he thought the GAO was out to get him. He claimed that certain members of his staff had been misquoted in the GAO reports and that from now on any information that came out of PRD would be very carefully screened by him beforehand. He said that if he gave us the information requested in our letter he was of the opinion it would be used against him.

I asked Dr. Hays if all this meant that we could not expect to receive this information. He replied, "I didn't say that." I then asked when we could expect to receive the information. He replied, "I have no idea." I asked if this meant that it might be 6 months before we could expect to obtain the information and he said, "I cannot tell you. I have no idea." At this point I thanked him and told him that I had another matter that I would like to discuss with him.

THOMAS H. HARRIS, Ph. D.,
Director, Division of Pesticide Registration.

Mr. GOODRICH. As stated by the USDA people they made it clear to Dr. Harris they thought he should supply firm scientific evidence or that his objections would be disregarded. The point we are trying to make is that some of these objections raise a fundamental policy issue of where the burden of proof of safety belongs and whether, when we object on the ground that a highly toxic rat poison is being registered, you need to support that with firm scientific evidence and if we do, if that is required, we want to understand from Agriculture what they would like us to present.

Mr. FOUNTAIN. Now, in this same agreement, 2E, insecticide procedure, reads and I quote:

In the event agreement is not reached among the Department representatives within 2 weeks of the initial objection, the matter will then be referred directly to the Secretary of the Department responsible for final action with such information, views and recommendations as the three Department representatives deem appropriate.

Has that ever been done?

Mr. DUGGAN. No, sir.

Mr. GOODRICH. This is one defect in the agreement that we were certainly focusing in on our discussions with the other Departments over possible revision, to make sure this mechnism is placed into operation.

Mr. FOUNTAIN. In other words, it evidently was contemplated here that the matter would be referred to the Department of Agriculture with such information, views, and recommendations as Interior and HEW as well as Agriculture may have.

Mr. GOODRICH. We didn't read this as authorizing the registration people to veto the objections instead of reaching an agreement. This is the point we are trying to have bare understanding among the three Departments on. This agreement also says, "The Secretary of the Department charged with final action may then avail himself of whatever

administrative and scientific review procedures seem appropriate under the circumstances," and the next line "the other two Departments will be notified in advance of the proposed final determination of the issues."

Mr. FOUNTAIN. Have you ever been notified of any proposed final determination of the issues which have been raised as a result of your objections?

Mr. DUGGAN. No, sir.

Mr. FOUNTAIN. Then of course it provides for this quarterly report.

Now on page 5 of your prepared statement you state that during the period of July 1, 1968 to June 1, 1969 you filed 177 objections to registrations.

Then you go on to say you don't know how many pesticide labels the Department of Agriculture has registered over HEW objections.

You mean in none of those 177 objections were you given information as to which of the labels concerning which those objections related were registered by Agriculture?

Dr. HARRIS. In that 177 I think there was one or more vapona labels and I believe that is it, where we withdrew the objection after reaching agreement that the product should have the statement on the label but except for that we don't know what happened to those objections.

Mr. FOUNTAIN. Would it be safe to say that notwithstanding the agreement, executed April 3, 1964 and signed by Secretary Freeman, Secretary Udall, and Secretary Celebrezze, that you just haven't had adequate, proper communications between yourselves and ARS?

Dr. HARRIS. We have daily contacts about individual questions but we haven't had these meetings provided for and we haven't met as often as we should have.

Mr. FOUNTAIN. Maybe these aren't easy questions but sometimes we need to know: Have you detected any resentment on the part of ARS of your agency filing objections?

Dr. HARRIS. I think there is some resentment. I was with the Pesticide Registration Division at the time this agreement was negotiated and at that time it was sort of looked upon as a necessary evil and they have never really looked very kindly on this agreement.

Mr. FOUNTAIN. They have a feeling you are maybe sort of supervising or snooping?

Dr. HARRIS. I wouldn't say at the top level. I think the top people would like to see this agreement work out very well. There has been some attitude at the lower levels that this is sort of a nuisance.

Mr. FOUNTAIN. Is it an institutional thing or personality?

Dr. HARRIS. I think it is an institutional thing myself.

Mr. FOUNTAIN. Those in the agency just have a feeling that this is their bailiwick and——

Dr. HARRIS. Going back to the time of my predecessor, Dr. Howard Bond, who was in from 1964 until I came in in 1966, he was regarded as sort of a major irritant and the Department of Agriculture objected to a lot of things. For example, he raised questions about nomenclature, proper chemical names, and they sort of resented that.

Mr. DUGGAN. I would think there is a difference here between the statutory authority which is vested in the Department of Agriculture in the advisory capacity that DHEW has found itself in. And this quite naturally raises problems.

Mr. FOUNTAIN. I understand that under the statute it is their responsibility and they might be reluctant to yield to objections of another agency. However, it seems to me that the two of you have qualified people and working together you can accomplish so much more. As a matter of fact, I think one of the most serious defects in the operation of the executive branch of the Federal Government, is the failure of a number of agencies which have related activities within their respective jurisdictions to coordinate and meet together and discuss mutual problems.

Mrs. Dwyer remembers this very well—when we investigated the so-called Billie Sol Estes cases, that is one of the things that stood out: lack of communications, lack of coordination, lack of knowledge on the part of Agriculture, what the Federal Bureau of Investigation knew or what the Department of Justice knew. And vice versa. And other agencies. It seems to me, even in a piecemeal fashion, if the committees in Congress and the subcommittees of the Government Operations Committee can do anything to improve that situation I think we will have helped improve our Federal system, at least this part of it. I think here is an example.

Mr. DUGGAN. In this connection, we have recognized this earlier. And earlier this month the Office of Product Safety which contains the Division of Pesticide Registration was instructed to report direct to the Commissioner instead of reporting to him through the Bureau office in an effort to get a better grasp and to be able to manage problems of this nature a bit better.

Mr. FOUNTAIN. I think there are some recommendations we made a long time ago to the Department of Agriculture also because we saw the need for so many people down here to get in touch with the Secretary and so seldom did men at the top have access to him on the things that they needed or the problems with which the lower branches were confronted.

Mrs. DWYER. May I ask a question? Do you feel all these three agencies should be under one roof under HEW instead of having to coordinate all these programs and to check back and forth. Would it not be better to have one boss where you would report to one head instead of going back and forth between the three agencies? Isn't this a health problem?

Mr. GOODRICH. If I may respond——

Mrs. DWYER. This is a loaded question to you I am sure. I should have asked Agriculture the same.

Mr. GOODRICH. There are great agricultural questions in this, in the use of pesticides. Legitimately USDA is concerned. Congress made a basic division between HEW and Agriculture back in 1954 when they passed the pesticide chemical amendment assigning to Agriculture the responsibility for evaluating agricultural usefulness of a variety of pesticides and specifying what levels of residues were likely to be encountered when the products were used and then assigned to HEW the health responsibility for establishing a safe tolerance. That mechanism has worked pretty good.

In 1963 the President's Science Advisory Committee identified in its report the very problem the chairman just mentioned, that Interior had problems with pesticides in fish and wildlife. They are concerned with maintenance of fish and wildlife and with the environment. So

they were legitimately interested in registration and patterns of use. So this report recommended the mechanism for better coordination. The agreement by the three Departments was drawn up to meet the recommendations of this high-level committee. The point we are making now is that that agreement simply hasn't worked as it is supposed to and when Food and Drug got this new responsibility of the PHS review of registration of labels, we have undertaken to review with Agriculture and Interior the agreement and to see that it works. If it doesn't work then it shouldn't be on the books. If it works it is going to have the means of allowing Agriculture its major input on the proper use of pesticides for a bountiful and healthful food supply and on HEW for the safety of the pesticide residues in foods and more broadly in products generally registered like things in the household, and at the same time allow U.S. Department of Interior to recommend against widespread applications that would have a bad influence on fish and wildlife.

Now every time we allow a tolerance for a pesticide in food, we check—Agriculture of course certifies whether it would be useful, what the residue would be, and we have a notation in our file that that pesticide residue has been checked out with Interior and they have no objection to it. That mechanism has worked out all right. We see problems with the registration.

Mrs. DWYER. Why can't you have agricultural experts within Food and Drug as well as Fish and Wildlife experts, Mr. Goodrich, so that instead of spreading out the responsibility among three different agencies where they all have to get together and coordinate. It seems to me there are so many people involved in this that many mistakes can be made.

Mr. GOODRICH. Well, there are a lot of people involved and mistakes can't be tolerated in this area because of the poisonous nature of the thing. They can't be tolerated for long. But the point—Agriculture has a responsibility for development, registration, safe use of pesticides on the farms and that would not really be a matter that ought to be transferred to Food and Drug nor do we think the responsibility should be transferred to Agriculture or a unit of that kind for establishing a safe tolerance in man's food.

Mrs. DWYER. But aren't these all household products really?

Mr. GOODRICH. Not at all. Some of them are sprayed in great amounts by airplanes, used on farms. There are some household products. This is one of the major points Dr. Harris' group has been objecting to. A container suitable for household use of rat poison—it is simply too dangerous to have around.

Mr. COPENHAVER. Mrs. Dwyer is suggesting that in those products that are household products that FDA should have responsibility over them or at least have some type of veto over their marketing prior to a registration being granted.

Mr. GOODRICH. This is why Dr. Harris' group was brought into it. Exactly. There shouldn't be a unilateral decision in USDA. There should be a separate health review by the Public Health Service before these household products were registered. Dr. Harris' group has been recommending right along that the more toxic pesticides not be allowed in household containers. I believe that is a major part of the objections that have been filed.

Mr. NAUGHTON. In your statement you indicate that in 1967 following discussions with USDA representatives and representatives of the sponsor, PHS decided to withdraw its objection.

Dr. HARRIS. Consultant of the Shell Co., Dr. Mitchell Zavon.

Mr. NAUGHTON. Where was the meeting held?

Dr. HARRIS. Dr. Simmons and Dr. Wayland Hayes in Atlanta held discussions with Dr. Mitchell Zavon. I believe they had discussed—we mentioned the matter in a meeting with Dr. Anderson in 1967 and I believe Dr. Simmons had some contact with the Department of Agriculture people too. I received a copy of a letter which he sent to Dr. Anderson pointing out the need for the statement on the label, "Don't use where infirmed individuals or infants are housed," but the discussions leading up to this compromise, if you will, took place in Atlanta between Dr. Simmons, Dr. Wayland Hayes, who was the principal toxicological adviser, and Dr. Mitchell Zavon, a representative of the Shell Chemical Co. I was notified in 1967 that we could withdraw the objection provided the label bore that statement. We continued to object, though, until we saw the statement on the label and that was the first part of 1969. We discontinued our objections when we began to see the statement on the label.

Mr. NAUGHTON. This was on the label submitted.

Dr. HARRIS. Right.

Mr. NAUGHTON. Have you had any indication when you submitted scientific data to USDA on a product to which you objected that it was accepted? Or have you ever actually submitted——

Dr. HARRIS. Yes, we objected to the registration of a product which is not yet registered. It was a highly toxic material. It was an agricultural product. That product has not yet been registered. We are still discussing the matter with both the registrant and Department of Agriculture. We have objected in the past and the product has not yet been registered.

Mr. NAUGHTON. You are not yet certain whether you will be successful on this? It just isn't on the market yet?

Dr. HARRIS. That is right.

Mr. NAUGHTON. Have there been any instances where you submitted scientific data or felt you had done so and it was rejected?

Dr. HARRIS. Yes. We gave reasons for one product—I am trving to recall it now—we objected to the registration of aramite and received a letter from Dr. Hays informing us that until we could produce evidence that this product produced cancers in human beings from skin contact that they would continue to register the product. This is a product regarded as a carcinogen. It produces cancers in experimental animals. That was the basis for our objection. We don't know how we can submit any better scientific evidence than to point out the product is a carcinogen. We were told without data showing this is a carcinogen by inhalation or skin absorption that registration would be continued. That is just one case that I recall.

Mr. NAUGHTON. Well, are there mandatory provisions in the law against the registration of carcinogens?

Dr. HARRIS. Not for noncrop uses.

Mr. NAUGHTON. Are there mandatory provisions for use on crops?

Dr. HARRIS. Yes.

Mr. NAUGHTON. Was this particular proposal that you objected to for use on crops?

Dr. HARRIS. This was a noncrop use. This was a use for mitocides on ornamentals, I believe.

Mr. NAUGHTON. Nonfood crop.

Dr. HARRIS. That's right. Aramite—minotrize is a herbicide for use in the control of poison ivy which is still registered and available for use.

Mr. NAUGHTON. In view of the testimony we have taken today and last May about deficiencies of labeling and the unknown number of products—but undoubtedly very large—which are on the market over the objection of the Public Health Service and now the Food and Drug Administration, what is your view as to whether or not it wouldn't be appropriate for some sort of project to be started for comprehensive review on a systematic basis to ascertain just what the situation is without waiting for these products to come up for their regular renewal?

Dr. HARRIS. I thought that was a question put to Dr. Hays. Isn't he going to submit a list of these products that are still registered over objections? I understood he was.

Mr. NAUGHTON. My understanding is in order for them to submit a list of products registered over objection they would have to search through every file. I think we would hesitate to ask them to go to all that work just to give us the number in view of the other things they could be doing.

Dr. HARRIS. It would be a big job.

Mr. NAUGHTON. However, if that project is going to be done it seems to me it should be done as part of a review to see which products should stay on the market and which would be the subject of actions to get them off. I would hope in the course of it they would look at the warning statements and the labels and see if they are consistent with one another.

Mr. DUGGAN. It is along these lines that the Commissioner's office has undertaken to review the entire system being used in reviewing pesticide labels.

Mr. NAUGHTON. What is the position of FDA with respect to the arsenicals which we discussed at some length today?

Dr. HARRIS. We have been objecting all along to the use of sodium arsenite and arsenic trioxide and other arsenicals around the home. Following publication in the Federal Register on sodium arsenite we sent Dr. Hays a letter commenting on that stating that we didn't have evidence to show that concentrations below 2 percent were safe so we continued to object and then I sent Dr. Hays a followup letter on that in May. I have a copy right here.

Mr. NAUGHTON. Would you provide that?

Dr. HARRIS. I believe he—that was an inquiry they hadn't received a reply to. In response to a telephone call I sent him a followup letter on May 19 I believe—I have a copy here.

Mr. NAUGHTON. Could you provide a copy for the subcommittee?

Dr. HARRIS. Yes.

Mr. NAUGHTON. Do you have any reason to believe that the product manufactured by the Pax Co. is any less dangerous than any of the others?

Dr. HARRIS. Arsenic trioxide is a solid. It is quite toxic. It is entirely possible for a 20-pound child to swallow many times the lethal dose of arsenic trioxide even though it is in a powder form.

Mr. NAUGHTON. Have accidents resulted primarily or to a large degree from the use of this material as a crab grass killer where it is on lawns and where children might be playing?

Dr. HARRIS. I don't really know. The sodium arsenite is a solution. That is probably the most hazardous.

Mr. NAUGHTON. This will be where someone would get a bottle of the stuff and take a swallow of it?

Dr. HARRIS. It was used for insect control as well as for control of crab grass.

Mr. FOUNTAIN. Did Pax Co. make any contact with you on——

Dr. HARRIS. No, they did not. We learned they had submitted some data to the Department of Agriculture and when I sent this last letter to Dr. Hays we told them we were requesting that data and that when we had a chance to look at it we may comment further, but we found nothing in that data that would dictate a change in our position with regard to the use——

Mr. FOUNTAIN. You examined the same data they had submitted to Agriculture?

Dr. HARRIS. Right.

Mr. NAUGHTON. Is it safe to assume when labels come over in the future for uses such as had been the practice for lindane in the past where there is an indication that the registered use will result in residues being left on food for which there is no tolerance, that you will object?

Mr. DUGGAN. Yes.

Mr. NAUGHTON. Do you have any intention of granting tolerances for use of insecticides in forms such as the No-Pest Strip which will result in residues being deposited on prepared food?

Mr. DUGGAN. I am sorry, I missed the first part of the question.

Mr. NAUGHTON. So far as you know is there any intention that tolerances will be granted for, let's say, so many parts of vapona on hamburger ready for serving?

Mr. DUGGAN. We have nothing in force at the present time on that.

Mr. NAUGHTON. You haven't granted any.

Mr. DUGGAN. No, and we have nothing before us.

Mr. NAUGHTON. Does your policy suggest you would grant such tolerances?

Mr. DUGGAN. We would look at it mighty carefully.

Mr. NAUGHTON. The emphasis has been on safety, but in the case of food adulteration, safety is not necessarily a part of it. Is that true?

Mr. DUGGAN. I am afraid I am——

Mr. NAUGHTON. In other words, if there is no tolerance for a particular pesticide chemical deposited on prepared food it doesn't make any difference whether it is safe or not, does it?

Mr. DUGGAN. It would be an adulterated food, yes.

Mr. NAUGHTON. Are there other factors that may come into adulteration in addition to contamination by poisonous and deleterious substances? For example, unsanitary conditions—in other words, other provisions of the law that are enforced by FDA with respect to food adulteration that might be involved in this type situation?

Mr. DUGGAN. Yes.

Mr. NAUGHTON. I think, for example, you have taken a position against fish flour made of whole fish.

Mr. DUGGAN. I think there is a regulation under that. The safety has been proven. The product is——

Mr. NAUGHTON. I may be behind the times but the original position you took on that, was that related to safety or the esthetics of the situation?

Mr. DUGGAN. There were both issues involved. Both issues were involved.

Mr. NAUGHTON. Do you anticipate that you will be contacting the State and local people with whom you work on food adulteration problems with respect to the questions that have been raised here on adulteration of food with pesticides? Lindane and vapona type situation.

Mr. DUGGAN. This has been our practice in the past, to keep in very close touch with the State and local people on that. As a matter of fact, I believe about 1953 the State and local people were notified by our Federal and State cooperation people about our concern about lindane vaporizers.

Mr. NAUGHTON. Agriculture has indicated they intend to abide by your position with respect to food adulteration. In the event that they don't follow through on that assurance, will you then take whatever action is necessary to insure that illegal activities are not allowed to continue?

Mr. DUGGAN. We will bring all the pressure to bear on this.

Mr. NAUGHTON. As a last resort, will you take action yourself? I don't think it should be necessary. It is your law. Will you enforce it?

Mr. DUGGAN. I would have to look at the circumstances.

Mr. NAUGHTON. You mean you don't intend to enforce your law?

Mr. DUGGAN. Yes, we intend to enforce it. I think we are doing a pretty good job of it.

Mr. NAUGHTON. Well, provide an answer for the record on that if you will, unless Mr. Goodrich would care to comment.

Mr. DUGGAN. Generally we would go to the State and local people and encourage them to enforce a local situation. If it was a national situation we would take action.

Mr. NAUGHTON. I don't disagree at all that the proper steps are first to take it up with Agriculture and then the State and local people and only as a last resort to go in and seize the adulterated food, but I am simply asking if you are prepared to follow this to the bitter end if it becomes necessary.

Mr. DUGGAN. If it becomes necessary.

Mr. FOUNTAIN. As I understand it, it was your feeling that this agreement had in mind giving you an opportunity to play a substantial part in any decision made with respect to pesticides used on food.

Mr. GOODRICH. The law did that. This agreement was over and above——

Mr. FOUNTAIN. Was to supplement that?

Mr. GOODRICH. Yes, sir.

Mr. FOUNTAIN. Maybe to implement it.

Mr. GOODRICH. Really to implement the report of the President's Science Advisory Committee which found a lack of coordination and it was to make sure the three Secretaries at the highest level put all their departments on the line of working together.

Now, what we find a failure in is that the procedures of bucking these issues up beyond the operating units has not been carried out and we are now exploring or propose to explore with Interior and USDA what will be necessary to really press these issues to a level where we can have a decision, not just a decision by one unit that has the power to approve the label.

Mr. FOUNTAIN. I use the word food. I meant household uses of pesticides. It seems to me that that is an area where your point of view should have tremendous impact upon the decision and maybe would be the controlling decision. When it comes to Agriculture and agricultural uses, that is what they are equipped for.

Well, thank you very much for coming up. We appreciate getting the benefit of your testimony.

(Whereupon, at 5:30 p.m., the subcommittee was recessed, subject to the call of the Chair.)

APPENDIXES

APPENDIX 1.—COMPTROLLER GENERAL'S REPORT TO THE CONGRESS ON NEED TO IMPROVE REGULATORY ENFORCEMENT PROCEDURES INVOLVING PESTICIDES, SEPTEMBER 10, 1968

REPORT TO THE CONGRESS

Need To Improve Regulatory Enforcement Procedures Involving Pesticides B-133192

Agricultural Research Service

Department of Agriculture

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

SEPT. 10, 1968

33-145 O—69——10

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-133192

To the President of the Senate and the
Speaker of the House of Representatives

Here is our report pointing out a need for the Agricultural Research Service of the Department of Agriculture to improve regulatory enforcement procedures involving pesticides.

Copies of this report are also being sent to the Director, Bureau of the Budget, and to the Secretary of Agriculture.

Elmer B. Staats

Comptroller General
of the United States

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

NEED TO IMPROVE REGULATORY ENFORCEMENT PROCEDURES INVOLVING PESTICIDES
Agricultural Research Service
Department of Agriculture B-133192

D I G E S T

WHY THE REVIEW WAS MADE

The Agricultural Research Service (ARS) is responsible for enforcing the Federal Insecticide, Fungicide, and Rodenticide Act--the basic consumer protection law in the area of pesticides. The law requires that all pesticide products shipped across a State line be safe and effective and be registered with ARS before being sold to the public.

To ensure that products being sold comply with the law, ARS obtains samples of products and tests them. Under the law, ARS may take action to remove products from the market, cancel the registration of products, and report to the Department of Justice for prosecution those who ship products that violate the law.

Because over 60,000 pesticide products are registered with ARS--virtually affecting every segment of the public--the General Accounting Office (GAO) wanted to find out how the law was being enforced to protect the public.

FINDINGS AND CONCLUSIONS

GAO found that, in taking action at locations against misbranded, adulterated, or unregistered products, ARS, with few possible exceptions, did not obtain quantity and shipping data to determine whether shipments of the same products were available to the public in other locations.

As a result, the actions taken may not have removed from the market products which, in some instances, were potentially harmful. (See pp. 8 to 13.)

GAO found that ARS operating guidelines did not include procedures for determining when shippers which had apparently violated the law would be reported to the Department of Justice for prosecution. There have been no actions by ARS to report violators of the law for prosecution in 13 years. This was true even in instances where repeated major violations of the law were cited by ARS and when shippers did not take satisfactory action to correct violations or ignored ARS notifications that prosecution was being contemplated. (See pp. 14 to 18.)

GAO found also that, at the time of its review, ARS was not publishing the notices of judgments of the courts ordering products off the market as required by the law. (See pp. 22 to 23.)

RECOMMENDATIONS OR SUGGESTIONS

GAO is recommending that ARS establish and implement procedures to provide for:

--obtaining shipping and product data,

--reporting violators of the law for prosecution, and

--publishing notices of judgments.

AGENCY ACTIONS

ARS has agreed to obtain the data necessary to support actions to remove products from the market and to use the data as a basis for obtaining samples and other documentary information on the product at every location possible, in order to remove the maximum amount of the product from the market.

ARS has revised its operating guidelines concerning shippers to now require that cases be forwarded for prosecution in instances where (1) the evidence indicates that the violation was willful, (2) the violation is of a serious nature and is the result of apparent gross negligence, or (3) the company has engaged in repeated violations.

ARS has made plans to publish the backlog of notices of judgments as soon as possible and to publish future notices at least every 6 months.

ISSUES FOR FURTHER CONSIDERATION

None.

LEGISLATIVE PROPOSALS

None.

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None.

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None.

INTRODUCTION

The General Accounting Office has reviewed the manner in which the Agricultural Research Service, Department of Agriculture, has carried out regulatory enforcement activities to prevent the interstate marketing of unregistered, adulterated, or misbranded pesticides. Our review, made pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67), was directed primarily toward an evaluation of the administration of pesticide enforcement activities, rather than to an evaluation of the administration of other Department or ARS activities involving pesticides.

Because over 60,000 pesticides products are registered with ARS--virtually affecting every segment of the public--we wanted to find out how ARS carries out regulatory enforcement activities to protect the public. Our review covered the enforcement actions initiated by ARS during fiscal year 1966 as well as related events occurring during the period February 1955 through May 1968. The scope of our review is described more fully on page 25.

BACKGROUND

It is the policy of the Department of Agriculture to encourage the use of those means of effective pest control which provide the least potential hazard to man and animals. According to the Department, pesticides are generally the most effective and, in many instances, the only available means for fighting pests that are destructive or endanger human health. In protecting man, animals, plants, farm and forest products, communities, and households against depredation by pests, the Department has a vital concern for the health and well-being of people who use pesticides and those who use products protected or treated by pesticides.

Statistics published by the Department indicate the importance of pesticides as well as the scope of their use in this country. The Department reported that during 1965 nearly $1 billion worth of pesticides were used in the protection of agricultural and forest products, that crop and

livestock production in the United States would drop by about 25 to 30 percent if pesticides were to be completely withdrawn from farm use, and that approximately 15 percent of all pesticides sold were purchased for home and garden use--a total of over 50 million pounds of product preparations.

Major programs of the Department--many of which are conducted in cooperation with State and local governments, other Federal agencies, educational and private organizations, and industry--are used in carrying out policy objectives. In addition to Federal laws and regulations to govern the movement and sale of pesticides in interstate commerce, there are programs of the Department which include maintaining quarantine barriers against foreign pests, monitoring pesticide residue levels in meat and poultry products, and conducting research and public education and information programs to find better and safer pest control methods and to promote the safe use of pesticides.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947 (7 U.S.C. 135-135k) provides the basic legal authority for regulating the interstate marketing of pesticides to protect the interests of both the user of pesticides and the consumer of products protected by pesticides. The Secretary of Agriculture is responsible for administering and enforcing the FIFRA. Authority for implementing the FIFRA is delegated to the Pesticides Regulation Division of the Department's Agricultural Research Service.

In addition to the FIFRA, related Federal laws concerned with safeguarding the public affect pesticide products. For instance, certain provisions of the Federal Food, Drug, and Cosmetic Act of 1938 (21 U.S.C. 301) directly affect the registration of pesticides. This act, which regulates the amount of residue that may remain after the use of pesticides on food commodities moving in interstate commerce, is administered by the Food and Drug Administration of the Department of Health, Education, and Welfare.

Also, individual States have laws and regulations on the sale of pesticides within State borders. An example is the Uniform State Insecticide, Fungicide, and Rodenticide Act developed by the Council of State Governments and adopted

by most States. The uniform State act, which parallels the FIFRA, facilitates cooperation between State and Federal officials in enforcing uniform regulations.

The FIFRA provides that every commercial pesticide formulation must be registered with the Department of Agriculture before it can be sold in interstate commerce. According to the Department, over 60,000 pesticide formulations based on more that 900 individual chemical compounds have been registered during the last two decades. Before registration is granted, a pesticide must meet tests which prove its claimed effectiveness against a particular pest or pests and demonstrate its safety when used as directed.

As part of the registration requirements, the Department of Agriculture regulates the contents of labels for pesticide products under the provisions of section 4 of the act. Federal regulations require that warning and cautionary statements be displayed on the labels of pesticides. The nature and scope of the safety claim on the label must conform to proven facts, and all labels must bear registration numbers indicating that the product has been accepted by the Department as adequate to permit both safe and effective use when container directions are followed.

To enforce compliance with the provisions of the FIFRA, ARS field inspectors, aided by deputized State inspectors, obtain sample products to be checked for violations of pesticide registration and labeling regulations. Products are submitted to Federal laboratories for analysis and testing. In this manner, ARS determines whether the products being marketed are as represented at the time of their original registration with the agency for marketing in interstate commerce.

Section 5 of the law provides authority to the Secretary of Agriculture for access to all records showing the delivery, movement, or holding of pesticide products, including quantities of shipments, dates of shipments and receipt of goods, and names of consignors or consignees of shipments.

Violations of the FIFRA include lack of Federal registration, adulteration, and misbranding of pesticide products.

In cases of violations of law, ARS is authorized by the FIFRA to (1) take action to remove the illegal shipment from the location where it is found (seizure action), (2) cancel the registration of the product, (3) report to the Department of Justice for criminal prosecution the person(s) alleged to be responsible for violating the act, or (4) use a combination of these actions. The act also requires ARS to notify the person(s) against whom criminal proceedings are contemplated.

The act provides that the seizure of products or the prosecution of violators is not required in the event that ARS determines that the violation is minor and the public interest will be served adequately by a written notice of warning. The act provides also for the publication of all judgments of the courts to seize products or to prosecute shippers under its authority.

In fiscal year 1966, ARS tested and reviewed 2,751 samples of pesticide products. As a result of the work performed, ARS reported that 750 samples were found to be in violation of the FIFRA and that 562 of the 750 samples were in major violation of the law. The samples determined by ARS to be in major violation of the law--cases that warranted such action as seizure or prosecution--represented about 20 percent of all the samples that were tested and reviewed in fiscal year 1966.

Enforcement actions taken in fiscal year 1966 included 106 actions by ARS to remove misbranded, adulterated, and unregistered products from the market as well as three actions by ARS to cancel the registration of products. During the same period there were no enforcement actions by ARS to report violators of the FIFRA for prosecution.

The principal officials of the Department of Agriculture responsible for the administration of pesticide enforcement activities are listed in appendix I to this report.

FINDINGS AND RECOMMENDATIONS

NEED TO ESTABLISH PROCEDURES INVOLVING PESTICIDE ENFORCEMENT ACTIONS

On the basis of our review, we believe that there is a need for ARS to establish procedures for strengthening pesticide enforcement actions that may be taken against misbranded, adulterated, or unregistered products or the shippers of such products.

We found that, in taking action against products, ARS, with few possible exceptions, did not obtain product quantity and location data to determine whether other shipments of the same misbranded, adulterated, or unregistered products were available to the public in other locations. As a result, the enforcement actions taken may not have removed violative and, in some instances, potentially harmful products from the market.

In our opinion, the product quantity and location data of the shippers is needed by ARS to (1) evaluate the adequacy of its enforcement actions, (2) determine the types of supplemental actions, if any, that may be necessary to protect the interests of the public, and (3) facilitate efforts to locate and remove undesirable products from the market.

We found also that ARS internal operating guidelines did not set forth the procedures to be used for determining when shippers that had allegedly violated the law would be reported to the Department of Justice for prosecution.

In this connection, we noted that there had been no enforcement actions by ARS to report violators of the FIFRA for prosecution in 13 years, even in instances where repeated major violations of the law were cited by the agency and when shippers did not take satisfactory action to correct violations or ignored ARS notifications that prosecution was being contemplated.

In our opinion, the lack of action by ARS to report firms for prosecution in serious or repeated cases could indicate to the shippers involved--as well as to other

shippers of pesticide products--that major violations of the law would be treated with minimum consequence. Moreover, any advantages attached to the value of prosecutions as a deterrent to future violations of the law would be nullified.

In June 1967, the Department of Agriculture proposed legislation to the Congress to amend the FIFRA which, if enacted and properly implemented, should tend to achieve generally more effective regulation of pesticides. The proposed legislation was pending in the Congress as of May 1968.

In our opinion, however, improved enforcement of the FIFRA also requires the establishment and implementation of procedures under existing provisions of the act. The details of our findings are discussed below.

Enforcement actions may not have resulted in the removal of misbranded, adulterated, or unregistered products from the market

Our review showed that, in taking 106 seizure actions in fiscal year 1966, ARS, with few possible exceptions, did not obtain product quantity and location data to determine whether other shipments of the same misbranded, adulterated, or unregistered products were available to the public in other locations. Similarly, we found that ARS action to cancel the registrations of certain products in fiscal year 1966 was not supplemented by action to obtain information bearing upon the quantities and locations of the products that had previously entered marketing channels. Section 5 of the FIFRA authorizes ARS to obtain such information from manufacturers, distributors, carriers, dealers, or any other person who sells, delivers, receives, or holds any product subject to the act.

Our review showed that ARS did not have procedures or standards for obtaining shipping and product information from the records of shippers of products. We found that generally it was ARS practice to remove from the market only the amount of the product, if any, on hand at the one retail or wholesale outlet where the sample was collected. We found further that ARS inspectors were using the

authority of section 5 of the FIFRA to establish from the records of the one retailer or wholesaler the fact that interstate shipment had been made of the particular stock from which the sample was taken.

According to ARS, the actions to seize products during fiscal year 1966 involved seven major types of pesticide products.

Type	Number of seizure actions
Agricultural insecticides	26
Disinfectants	38
Fungicides	1
Herbicides	13
Animal insecticides	12
Miscellaneous insecticides	14
Animal biology	2
Total	106

Also, ARS reported in program publications that the actions to take products off the market were a significant part of the protection being given the public under the provisions of the FIFRA.

We found that 84 of the 106 seizure actions (involving 79 different products) resulted in the removal of part or all of the stock from the locations from which samples were taken; however, in 22 of the 106 seizure actions (about one out of every five such actions) the removal from the market of any quantity of the product was not accomplished inasmuch as the product was no longer on the shelves or in storage at the one location where the sample was collected when the seizure was attempted.

We found further that the 79 different products which had been seized were seized at only 80 different wholesale or retail outlets throughout the United States and that ARS did not obtain shipping location and product quantity information from the records of shippers of products, even though the products could be sold nationally.

An example follows which we believe illustrates the need for ARS to better use its authority to obtain shipping location and product quantity information in order to provide better protection to the public.

On March 9, 1966, ARS seized 11 one-gallon containers of a liquid spray insecticide from an outlet in Santa Fe, New Mexico, because the product was contaminated with a toxic ingredient not named on the container. Subsequent to the seizure, the manufacturer of the product was notified by ARS of the violation of the FIFRA. On March 30, 1966, the manufacturer advised ARS that the wrong label had been applied to the product and that procedures had been revised to avoid repetition of the error.

On April 22, 1966, ARS informed the manufacturer that the mislabeling of the product had resulted in a very dangerous situation since a purchaser would be using a much more hazardous chemical than he believed he had purchased. ARS stated that the product was not acceptable as labeled because of the increased danger of inhalation and skin absorption and requested more information regarding the procedures taken to avoid a repetition. In addition, ARS asked for information regarding the steps taken to recall any other outstanding stocks that may have been similarly mislabeled.

The manufacturer's reply to ARS on May 18, 1966, outlined the steps that had been taken to prevent a recurrence of the violation but contained no information on actions taken to recall any other outstanding stocks of the product that may have been similarly mislabeled. Despite the absence of this information, ARS notified the manufacturer on May 27, 1966, that any further action with respect to the case need not be taken.

ARS closed the case on June 7, 1966, without establishing the quantity or location of similarly deficient products that may have been available to the public.

Our review showed that, in addition to seizures in fiscal year 1966, three enforcement actions were taken by ARS involving the cancellation of certain uses of registered products containing specific chemical ingredients.

For instance, ARS canceled the registrations for use on certain crops of 475 products containing the chemicals aldrin and dieldrin when new scientific developments became available to justify changes in the registered labeling of products containing those chemicals. We found further that, in the interest of public safety, ARS canceled the registrations of 58 products containing the chemical thallium.

Our review of the cancellation of the registrations of the products containing thallium showed that the action was taken by ARS because the general use of such products had resulted in numerous accidents. According to ARS, thallium had been used in bait material for the control of insects and rodents for a number of years; however, a number of deaths had occurred, principally in children, as a result of accidental consumption of the bait material.

In June 1960, ARS took action to limit the thallium content of products in an attempt to reduce the possibility of fatal accidents associated with the use of such products. In spite of the limitation, deaths continued to occur as a result of accidental ingestion of the products. In addition, statistics of the Public Health Service indicated that there were about 400 reported cases of thallium poisoning of children during 1962 and 1963.

On August 1, 1965, ARS notified manufacturers, formulators, distributors, and registrants that the registrations of products containing thallium were being canceled. The cancellations involved 45 registrants and 58 thallium products. According to ARS, the action was taken as a result of the continuing number of accidents associated with the general use of the products. The effective date of the cancellation of the registrations of the products containing thallium was 30 days after the registrants received the notice of August 1, 1965.

Our review showed that the action in August 1965 to cancel the registration of the products involved was not supplemented by action to obtain information on the quantities and locations of products that had previously entered marketing channels. We found that, subsequent to the cancellation of the registrations, thallium products continued to be available for public consumption and that

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efforts ARS made to protect the public, such as attempts to locate thallium products, were being made without knowing the locations or quantities of the products involved. We found also that a product containing thallium was still available to the public in January 1968 and that the extent and duration to which such products remained available to the public were unknown.

Our review showed that in November 1966--14 months after the cancellation of registrations--an ARS memorandum of instructions to agency field inspectors discussing the availability of thallium products stated that:

> "Recent reports indicate that these products are still available at the retail level. Please increase your surveillance of hardware, drug, grocery, novelty stores etc. to determine if they are still on the shelves. If encountered and the shipment was made prior to August 1965, you may be able to get the dealer to voluntarily destroy the merchandise. If not, you should bring the matter to the attention of the local authorities. If the shipment was made after August 1965, we can take action based on a violation of the Federal Insecticide, Fungicide, and Rodenticide Act. In either case, you should check the wholesaler or distributor from whom purchased to determine if larger sized lots are available. Seizure action will be taken when possible." (Underscoring supplied.)

Our review showed that ARS inspectors located 15 lots of products containing thallium during the period January 1 through June 30, 1967. ARS identified three of the 15 lots as shipments made subsequent to September 1, 1965, and took action to remove them from the market. We found further that the remaining 12 lots were identified by ARS as shipments made prior to September 1965 and that six of the 12 lots were voluntarily destroyed by the dealer, three lots were referred to State authorities when the dealer refused to voluntarily destroy the merchandise, and three lots were removed from sale by the dealer pending return to the shipper for credit.

On August 9, 1967, a representative of the General Accounting Office visited about 20 retail stores in Washington, D.C., to determine whether products were being sold in violation of Federal law. As a result, about 100 packages of a product containing thallium were located and brought to the attention of ARS. The merchandise, which had been on the market prior to the cancellation of the registrations in 1965 was removed from the market on August 31, 1967.

After notifying ARS of the availability of the thallium products, we noted that an agency inspector canvassed 22 additional retail stores in Washington, D.C., and suburban Maryland. The inspector located products containing thallium in six, or about 27 percent, of the 22 outlets visited. Furthermore, on January 29, 1968, a representative of our Office located about 65 more packages of a product containing thallium in suburban Maryland. The products in these instances--as previously--had been in marketing channels prior to the cancellation of the registrations.

We were informed by ARS officials that, because of the continuing availability to the public of thallium products, three firms were requested in 1967 to make an effort to locate and remove from the market stocks of products containing thallium. We were informed also that ARS would continue its surveillance for thallium products until such products could no longer be found.

We believe that, under the provisions of the FIFRA, appropriate information pertaining to locations and quantities of products could have been obtained by ARS in conjunction with its enforcement actions to seize products and to cancel the registrations of the thallium products. In our opinion, such information would be needed by ARS to (1) evaluate the adequacy of its enforcement actions, (2) determine the types of supplemental actions, if any, that may be necessary to protect the interests of the public, and (3) facilitate efforts to locate and remove undesirable products from the market.

Alleged violators of the FIFRA not reported for prosecution

Our review showed that during the 13-year period from February 1955 through February 1968, alleged violators of the FIFRA were not reported to the Department of Justice for prosecution even though, in some instances, prosecution of such violators, in our opinion, appeared warranted.

We found that, during fiscal year 1966, ARS notified 242 shippers of pesticide products that criminal proceedings against them were contemplated. The charges to be brought against the 242 shippers involved 456 samples of products that were determined by ARS to be in major violation of the act. We found that 77, or about 32 percent, of the shippers were responsible for 291, or about 64 percent, of the samples violating the law. According to ARS records, each of the 77 shippers had violated the law on more than one occasion in fiscal year 1966 and two of the shippers were known by ARS to have violated the law on 20 separate occasions during this period, as illustrated by the following table.

Number of shippers	Number of samples in violation per shipper
2	20
1	10
1	8
4	7
3	6
6	5
12	4
13	3
35	2
77	

In our opinion, such statistics indicate that misbranded, adulterated, or unregistered products are shipped most often by the same firms.

According to ARS internal operating guidelines, action to report violators for prosecution is resorted to only

when all other methods have failed to obtain required corrections, such as when a firm has had several major violations and apparently has made little or no effort to bring its products into compliance with the act. In accordance with section 6.c. of the FIFRA, the purpose of the notification of contemplated prosecution is to list the alleged violations and to offer a firm an opportunity to make any explanation desired within 20 days.

During our review, we noted a lack of action by ARS to report firms for prosecution even in instances when notifications of contemplated prosecutions were ignored.

For instance, our review showed that ARS collected a sample of a hospital disinfectant in Portland, Oregon, on January 25, 1965. The shipping records collected with the sample indicated that the product was shipped to the dealer in Portland from the manufacturer in Chicago, Illinois, during June and October 1964. The sample, a report of the collection, and shipping records related to the containers at the one location in Portland were sent on January 29, 1965, to an ARS bacteriology laboratory in Beltsville, Maryland.

On February 19, 1965, ARS completed its analysis of the sample. The analysis showed that the product was in violation of the FIFRA because, when used as directed, it could not be relied upon to kill a bacteria (staphylococcus) that causes drug-resistant bacterial infection, although this claim was made on the label. On March 4, 1965, ARS, as a result of the analysis, determined that the product was not effective as a hospital disinfectant and that enforcement action should be instituted.

On June 1, 1965, ARS informed the shipper of the disinfectant that prosecution under the provisions of the FIFRA was contemplated for shipping a product in violation of the law. In response to ARS, the shipper requested on August 3, 1965, that a sample of the deficient product be made available for analysis so that a confirmation or denial of the ARS charges could be made.

On September 14, 1965, ARS sent a sample of the deficient product to the shipper and informed him that his case

would be held open for the time necessary to study and comment on the sample. In a letter dated December 20, 1965, ARS again informed the shipper that the case was being held open and that the receipt of his explanation to the contemplated prosecution was pending. We noted, however, that in a memorandum dated March 4, 1966, ARS, in discussing the contemplated prosecution, concluded that the examination of samples from future shipments of the product should be made. ARS stated that:

> "A subsample of our official sample was forwarded on September 14, 1965 for his [shipper's] confirmation of sample failure. We have not received any reply to this letter nor to our follow-up letter of December 20, 1965. In view of the fact that the firm has had ample time to run tests to confirm our findings to their satisfaction, and has not replied to our follow-up letters above, it is recommended that this case be placed in Temporary Abeyance [held open] pending examination of samples from future shipments of the product."

Our review showed that on June 15, 1965, ARS had collected another sample of the hospital disinfectant from a different shipment to the same dealer in Portland, Oregon. The sample was sent on June 18, 1965, to the bacteriological laboratory in Beltsville, Maryland. On July 16, 1965, the laboratory reported that the product was again in violation of the FIFRA in that the labeling made claims to being a disinfectant which kills an antibiotic resistant bacteria; whereas, when used as directed, the product would not kill the bacteria or disinfect hospital instruments, utensils, and equipment or hospital operating rooms, delivery rooms, nurseries, maternity wards, and patient rooms. The laboratory report recommended that the product be seized and the shipper of the product be notified of ARS's intention of prosecuting him in an action separate from the seizure of the product.

On July 30, 1965, ARS, in justifying the need for the enforcement actions, stated that:

> "The product is represented as a hospital disinfectant. *** When used as directed, the product would not be effective as a hospital disinfectant. A previous sample of this product I.D. No. 47076, was obtained at the same dealer and found to be ineffective."

On August 30, 1965, ARS informed the shipper that prosecution under the provisions of the FIFRA was also contemplated for shipping the second disinfectant. In a follow-up to this contemplated prosecution, ARS, in an October 22, 1965, letter to the shipper, stated that:

> "No reply has been received and the matter is being called to your attention in the belief that it may have been overlooked. We should point out that once a regulatory action of this type has been initiated, we do not have the authority to hold the matter open indefinitely."

We noted, however, that on March 22, 1966, ARS again determined that additional samples should be collected and that the case would be held open.

Our review showed that during fiscal year 1966 ARS collected 127 samples of products manufactured by the shipper, of which 36, or about 28 percent, were determined by ARS to be in violation of the FIFRA. Our review showed further that the shipper was notified of contemplated prosecutions on six separate occasions involving 20 samples that were determined by ARS to be in major violation of the law. We found, however, that in no instance was the enforcement action taken to report the shipper to the Department of Justice for prosecution. Moreover, we noted that, from the end of fiscal year 1966, the shipper of the hospital disinfectant had continued to violate the provisions of the FIFRA.

For instance, we noted that in October 1966, ARS canceled the registration of the hospital disinfectant. The cancellation was made pursuant to the failure of the manufacturer to comply with revised labeling requirements of the FIFRA. The changed labeling requirements were brought about by an amendment to the FIFRA on May 12, 1964, and

revisions of the regulations under the FIFRA. The manufacturer was notified of the new labeling requirements on September 15, 1964, December 7, 1965, and August 1, 1966. Nevertheless, our review showed that in August 1967, ARS collected a sample of the unregistered product that was shipped in interstate commerce during May 1967.

The sample was tested by ARS on September 21, 1967. The laboratory tests showed--as on previous occasions--that, in addition to being unregistered, when the product was used as directed, it could not be relied upon as a hospital disinfectant. The laboratory report again recommended that the shipper be informed of a contemplated prosecution. We found, however, that on January 23, 1968, ARS determined that this case also would be held open pending the examination of additional samples.

Our review showed that in other instances also shippers ignored ARS notices of contemplated proceedings or did not explain the causes of violations to the satisfaction of the agency. We noted, however, that the ARS internal operating guidelines did not set forth the follow-on procedures to be used to determine when shippers that had allegedly violated the law would be reported to the Department of Justice for prosecution.

We believe that the lack of enforcement action by ARS concerning the prosecution of shippers could impair the achievement of the objective of pesticide regulation enforcement to protect the interest of the public. In our opinion, the lack of action by ARS to report firms for prosecution in serious or repeated cases could indicate to the shippers involved--as well as to other shippers of pesticide products--that major violations of the law would be treated with minimum consequence. Moreover, any advantages attached to the value of prosecutions as a deterrent to future violations of the law would be nullified.

Legislation proposed
to improve regulation of pesticides

Our review showed that legislation proposed by the Department of Agriculture to amend the FIFRA to provide for

more effective regulation under the act was introduced in the Senate on June 29, 1967 (S. 2057, 90th Cong.), and in the House of Representatives on July 27, 1967 (H.R. 11846, 90th Cong.).

The identical legislation introduced in both houses would add new tools with which to enforce the FIFRA. The amendment, which was pending in the Congress as of May 1968, would require registration of all establishments engaged in making pesticides; permit inspection of establishments as well as conveyances being used to transport, sell, or hold pesticides in interstate commerce; and provide additional controls, civil penalties, and injunctive authority to enforce and restrain violations of the act.

According to the Department, the provision for registering establishments calls for the suspension of such registration if the establishments are not conducting operations in accordance with good manufacturing practice. Authority for factory inspection would make it possible for the Department to inspect the operations of a company to ascertain whether proper materials, precautions, and controls were being used.

The Department, in discussing the proposed legislation, reported to the Congress that, under the provision for civil penalties, violations could be handled which were of sufficient importance to warrant some action other than a written notice of warning, as presently provided for in the FIFRA, but not of such nature as to warrant criminal prosecution. Moreover, as stated by the Department, injunctive authority would make it possible to more effectively carry out the responsibility of the Department to prevent the interstate movement of pesticides.

On the basis of our review, we believe that the legislation proposed by the Department would add valuable tools with which to enforce the FIFRA and, if enacted and properly implemented, should tend to achieve more effective regulation of pesticides. In our opinion, however, achieving proper enforcement of the FIFRA should include also the implementation of improved procedures under existing provisions of the law.

Conclusion

On the basis of our review, we believe that there is a need for ARS to establish procedures for strengthening pesticide enforcement actions that may be taken against misbranded, adulterated, or unregistered products or the shippers of such products.

We found that, in taking actions against products, ARS, with few possible exceptions, did not obtain product quantity and location data to determine whether other shipments of the same misbranded, adulterated, or unregistered products were available to the public in other locations.

In our opinion, the product quantity and location data of the shippers is needed by ARS to (1) evaluate the adequacy of its enforcement actions, (2) determine the types of supplemental actions, if any, that may be necessary to protect the interests of the public, and (3) facilitate efforts to locate and remove undesirable products from the market.

We found also that ARS internal operating guidelines did not set forth the procedures to be used for determining when shippers that have allegedly violated the law would be reported to the Department of Justice for prosecution.

In our opinion, the lack of action by ARS to report firms for prosecution in serious or repeated cases could indicate to the shippers involved--as well as to other shippers of pesticide products--that major violations of the law would be treated with minimum consequence. Moreover, any advantages attached to the value of prosecutions as a deterrent to future violations of the law would be nullified.

Recommendation to the Administrator,
Agricultural Research Service

We recommend to the Administrator of ARS that procedures be established and implemented involving the taking of enforcement actions, particularly with respect to (1) obtaining shipping and product data and (2) reporting violators of Federal law for prosecution.

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By letter dated May 22, 1968 (see app. II), the Acting Administrator, ARS, commented on the need for establishing procedures involving pesticide enforcement actions, as discussed in this report, and agreed with our findings and recommendations.

In outlining the steps taken with respect to removing violative products from the market, the Acting Administrator commented on the use of seizure actions as well as the use of recalls by the manufacturers of products. The Acting Administrator stated that, in instances where a shipper refused to voluntarily recall a product from the market, ARS would (1) obtain data concerning shipments of the product from the shipper or manufacturer as a first step in obtaining the evidence necessary to support seizure actions and (2) use shipping data as a basis for obtaining samples and other documentary information relative to the product at every location possible with a view toward initiating the maximum number of seizure actions.

In commenting on the need to establish procedures involving the prosecution of shippers, the Acting Administrator stated that the present operating guidelines require that cases be forwarded for prosecution in instances where (1) the evidence indicates that the violation was willfull, (2) the violation is of a serious nature and is the result of apparent gross negligence, or (3) the company has engaged in repeated violations.

The Acting Administrator stated also that a prosecution file related to the shipper of the hospital disinfectant discussed on pages 15 to 18 of this report had been prepared by ARS and was currently being processed.

NEED TO ESTABLISH PROCEDURES INVOLVING PUBLICATIONS OF NOTICES OF JUDGMENTS

On the basis of our review, we believe that there is a need for ARS to establish procedures which specify the frequency of publishing notices of judgments of the courts in cases arising under the provisions of the FIFRA. Section 6.e. of the FIFRA requires that the Secretary of Agriculture, by publication in such manner as he may prescribe, give notice of all judgments entered in actions instituted under the authority of the act.

According to ARS, which has been delegated the authority of prescribing procedures necessary for the publication of the judgments, the purpose of the publications is to disseminate to the public--principally through libraries--the results of court decisions involving pesticide products and the shippers of pesticide products. The publications include information as to the specific violations of the FIFRA, the dates various legal actions are taken, and the final decree of the court regarding the disposition of seized goods and the penalty imposed on the violator.

Our review showed that ARS had not established procedures to implement the provisions of section 6.e. of the FIFRA. We found that, from the inception of the FIFRA in 1947, 18 publications summarizing the results of 515 judgments had been issued by ARS. Our review of the 10 most recent publications showed that such documents had been approved for publication at intervals averaging about 6 months. We noted also that the number of judgments per publication ranged from a low of 15 to a high of 35 and that a total of 245 judgments had been summarized in the documents.

We found, however, that the last such document had been approved for publication by ARS in November 1964 and that as of December 1967 there was an accumulation of about 250 judgments of various Federal district courts throughout the country which had not been published. There follows, for this period, a summary showing for 6-month periods the number of unpublished judgments that became available for dissemination.

From		Through		Unpublished
Month	Year	Month	Year	judgments
Prior to January	1965			32
January	1965	June	1965	20
July	1965	December	1965	21
January	1966	June	1966	34
July	1966	December	1966	27
January	1967	June	1967	59
July	1967	December	1967	57
Total				250

Moreover, we noted, from projections by ARS, that enforcement actions involving future judgments of the courts are expected to total about 900 during the period of fiscal year 1968 through fiscal year 1970.

On October 26, 1967, we were informed by an ARS official that continuation of the publications had been neglected after the employee assigned to compiling information necessary to the issuance of the documents had retired. However, subsequent to our bringing the matter to the attention of ARS, we were informed further that action to resume the publications was being taken.

It is our view that disseminating information on decisions involving pesticide products and shippers of pesticide products that violate the law contributes to the education and welfare of users and prospective users of pesticides as well as of other segments of the public. We therefore believe that procedures should be established by ARS to ensure that such information is published and made available, to the maximum extent practicable, on a frequent and regular basis.

Recommendation to the Administrator, Agricultural Research Service

We recommend to the Administrator of ARS that procedures specifying the frequency of future publications of notices of judgments be established and implemented.

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In his letter of May 22, 1968, the Acting Administrator informed us that he anticipated that the backlog of notices of judgments would be published by December 31, 1968, and that thereafter ARS would publish notices of judgments at intervals of not more than 6 months.

SCOPE OF REVIEW

We reviewed (1) the legislative history and authority which established the pesticide enforcement activity, (2) pertinent policies, procedures, and practices established by the Department and ARS for carrying out enforcement actions to seize products, prosecute shippers, and cancel product registrations, and (3) certain information of the Food and Drug Administration and the Public Health Service, Department of Health, Education, and Welfare related to enforcement activities.

Our review, performed principally in the offices of the Pesticides Regulation Division of ARS at Washington, D.C., included visits to retail outlets selling pesticides in the States of Maryland and Virginia and in the District of Columbia.

APPENDIXES

APPENDIX I

PRINCIPAL OFFICIALS OF

THE DEPARTMENT OF AGRICULTURE

RESPONSIBLE FOR ADMINISTRATION

OF ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
DEPARTMENT OF AGRICULTURE		
SECRETARY OF AGRICULTURE:		
Orville L. Freeman	Jan. 1961	Present
DIRECTOR OF SCIENCE AND EDUCATION:		
Nyle C. Brady	Dec. 1963	Aug. 1965
George L. Mehren (note a)	Sept. 1965	Present
AGRICULTURAL RESEARCH SERVICE		
ADMINISTRATOR:		
Byron T. Shaw	June 1954	Mar. 1965
George W. Irving, Jr.	Mar. 1965	Present
DEPUTY ADMINISTRATOR, REGULATORY AND CONTROL:		
Robert J. Anderson	Mar. 1963	Nov. 1966
Francis J. Mulhern (acting)	Jan. 1967	May 1967
Francis J. Mulhern	May 1967	Present
DIRECTOR, PESTICIDES REGULATION DIVISION:		
Justus C. Ward	Nov. 1961	June 1966
Harry W. Hays	July 1966	Present

[a]By a memorandum dated October 5, 1965, the Secretary of Agriculture delegated the duties and responsibilities of the Director of Science and Education to Dr. George L. Mehren, Assistant Secretary for Marketing and Consumer Services, pending the appointment of a new Director.

APPENDIX II

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE
WASHINGTON, D.C. 20250

OFFICE OF ADMINISTRATOR

MAY 22, 1968

Mr. Victor L. Lowe
Associate Director
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Lowe:

This is in response to your request for our comments on the draft of your proposed report to the Congress on the need to improve regulatory enforcement procedures involving pesticides, Agricultural Research Service, Department of Agriculture.

First of all, let me say that we appreciate the opportunity to comment on your report. We also appreciate the spirit in which your investigation was conducted and the attitude of the members of your staff who participated in the investigation. Your investigation is in harmony with, and supplementary to, our own continuing study of our enforcement policy and procedures under the Federal Insecticide, Fungicide, and Rodenticide Act. And the objectives of your recommendations, as set forth in your report, coincide with our aims in effectively carrying out the provisions of the Act. I am sure that the findings in your report will be of benefit to us in our future evaluations of enforcement activities under the Act.

The principal findings in your report are (1) that enforcement actions may not have removed misbranded, adulterated, or unregistered products from the market, (2) that repeated violators of the Federal Insecticide, Fungicide, and Rodenticide Act have not been prosecuted, (3) that proposed legislation, if enacted and properly implemented, would achieve generally more effective regulation of pesticides, and (4) that there is a need to establish procedures involving publications of notices of judgments. We cannot disagree with these findings. In fact, we have recognized the need for more effective enforcement action in the areas covered by your report and have taken steps which we believe will greatly strengthen and improve our enforcement program in these areas.

In your meetings on the proposed report with members of our staff, you have emphasized the desirability for a direct response to the report. In view of what has been said above, we do not feel it necessary to comment in detail on your basic findings. Instead, we believe that the most direct response to your report is to inform you of the significant

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changes which have been made in our enforcement policy and practice since the period covered by your investigation, and of our present enforcement activities as they relate to the matters referred to in the report.

In setting forth certain of the changes which have taken place in our enforcement policy and practice, we wish to emphasize that we are still in a transitional stage. As you are aware, the changes which we are making require time--and personnel--to fully accomplish. Because of present personnel limitations and budget questions, we are unable to accurately pinpoint how and when we will be able to completely implement the enforcement policy which is presently in effect. However, we hope the discussion below will not only inform you of our present policy and practice in the areas covered by your report, but also inform you of additional steps we intend to take in these areas.

I. Removal of Violative Products from Market

A. Seizure and Recall Actions

Section 9 of the Act authorizes the seizure of products found to be in violation of certain provisions of the Act. This is the only direct authority in the Act for the removal of violative products from channels of trade.

Seizure actions under the Act have increased as our sampling program and analytical work have increased. In fiscal 1967, 189 seizure actions were initiated. During the first six months of fiscal 1968, 240 seizures were processed. We believe that this increased seizure activity has had an effect beyond the removal of violative products from the market. In our opinion, there has been a commensurate increase in the awareness on the part of industry that enforcement is being emphasized under the Act. This opinion is based primarily upon the numerous telephone calls and meetings we have had relative to our seizure actions, and the representations by members of industry of their desire to cooperate with the Department in our efforts to carry out the provisions of the Act.

However, in spite of this notable increase in the number of seizures under the Act, we recognize that the effectiveness of seizure actions is limited by the nature of the enforcement action itself. Due to the length of time which it takes to process actions in this Department and the United States Attorneys' offices, there are inevitably a certain number of cases in which seizure action is recommended but where no product is found to seize. In addition, only the particular amount of product from which a sample is obtained is affected by any one seizure action.

During the past year we have reviewed, and we are continuing to review, our seizure program with a view toward making more effective use of our seizure authority. We do not believe that exercise of our seizure authority, in and of itself, can effectively remove all violative products from the market. We do believe, however, that the seizure authority can be an effective enforcement tool when used in conjunction with, and as an integral part of, other enforcement procedures.

The Federal Insecticide, Fungicide, and Rodenticide Act contains no provision relating to the recall of products. However, we believe that cooperative action by a manufacturer in recalling defective or hazardous products is the most efficient and effective means of removing such products from channels of trade.

For our purposes, recalls fall into two general categories--company initiated recalls and Pesticides Regulation Division initiated recalls. A company initiated recall is one in which the manufacturer takes steps to withdraw the product from the market, without a request from the Pesticides Regulation Division, upon being informed of the Division's findings with respect to a particular shipment. Attachment 1 [See GAO note] lists thirty instances, primarily in the months of November and December 1967, where companies have voluntarily withdrawn products from the market, or brought outstanding shipments of products into compliance with the Act, following citations. Such recalls have noticeably increased in recent months. We expect this type of voluntary cooperative action on the part of industry to further increase.

A Pesticides Regulation Division initiated recall is one in which the Division specifically requests a manufacturer to withdraw a product from channels of trade. Normally, such a request to a manufacturer would not be made until documentary evidence was available to support strong legal action. In extreme cases, such as a case involving a potentially hazardous product, we would make such a request without the necessary documentary evidence to support legal action.

During the last six months of 1967, four recalls of products were initiated by manufacturers at our request:

1. Wyandotte Chemicals Corporation--Loxene and Loxsit (pentachlorophenol). All salesmen, distributors, and customers of company were directly contacted and 21,450 pounds of Loxene and 9,187 pounds of Loxsit were returned.

2. American Riverside Company, Inc.,--U-MIL-O-IMC (sodium pentachlorophenate). All salesmen, distributors, and customers of company were directly contacted and 385 gallons of this product withdrawn.

3. F. C. Stuartevant Company--Lilly's Ant Cups (sodium arsenate--ant bait packaged in bottle caps). All distributors and dealers of company contacted. Interim report shows that 1,511 dozen returned to company and 14,760 units being held by company for destruction.

4. O. E. Linck Company--Tat-Mo-Go (strychnine sulphate). Recall letters sent to 128 consignees. Interim report shows 469 dozen returned to company. Company inventory of 40,000 packaged units being held for relabeling.

GAO note: Agency attachment not included in this report.

In the above actions, the recalls were supervised by a Supervisory Inspector of the Pesticides Regulation Division. This included supervision of company action in sending recall notices to all consignees or customers, and the reviewing of replies and responses to the recall action. Destruction, relabeling or other disposition of the returned merchandise is also under the supervision of our Supervisory Inspectors. The completeness of the action in the above cases, as in any other recall action, is judged upon the basis of the responses received to the recall notices.

We intend to make increased use of recalls in our enforcement program. It is our intention to initiate a recall action in cases involving products which are hazardous or completely ineffective. It is believed that increased use of the recall procedure is consistent with our enforcement objective of obtaining maximum public protection with the least expenditure of public funds.

In your report it is recommended that procedures be established with respect to obtaining product shipping and location data to assure that pesticide products which represent the greatest health hazard are afforded the necessary depth of coverage. The obtaining of this data would become important if a shipper refused to voluntarily recall a product in a situation where we felt the recall of the product from the market was necessary. In any such case, we would obtain data concerning shipments of the product from the shipper or manufacturer as a first step in obtaining the evidence necessary to support seizure actions. We would use shipping data as a basis for obtaining samples and other documentary information relative to the product at every location possible with a view toward initiating the maximum number of seizure actions.

II. Criminal Procedure

A. Citations

Our citation procedure (notice of contemplated proceedings) is part of the criminal procedures set forth in Section 6 of the Act. This Section provides that whenever economic poisons or devices are found to be in violation of the Act, a notice shall be given to the person against whom criminal proceedings are contemplated. This citation procedure is applicable to all criminal violations of the Act and is a statutory prerequisite to criminal prosecution. The primary purpose of this procedure is to give the person cited an opportunity to submit any facts or explanation relevant to the alleged violation.

Because of the nature and purpose of the citation procedure, we believe it to be our most effective enforcement tool. However, to be effective in accomplishing the purposes of the Act, we also believe it must be utilized as something more than a routine notice of violation--and the person cited must be aware of the true purpose and nature of the citation.

We carefully review the answer to each citation from the standpoint of (1) the nature of the violation, (2) the explanation given by the person cited as to the reason for the alleged violation, and (3) the assurances given that such violation will not recur. These matters are also emphasized in all our meetings and discussions with industry representatives concerning the alleged violation. With the setting up of a section to handle prosecutions, we have emphasized these matters in our citation charge sheets (See Attachment 2). [See GAO note.]

Under Section 6 of the Act we are not required to send to the Department of Justice for prosecution any matter where we make a determination that the public interest will be served by a suitable written notice of warning. We are now specifically calling to the attention of the person cited that our "closing" letter is intended to serve as a notice of warning under Section 6 (See Attachment 3). [See GAO note.]

We believe that through our citation procedure we can most effectively obtain corrective action, not only with respect to the particular product involved, but also with respect to the entire product line of the company cited. For example, we have been informed by companies that as a result of our citations they have taken steps to (1) review all manufacturing procedures to reduce or eliminate contaminations, (2) set up quality controls to assure the effectiveness of their products, and (3) initiate a complete label review for all products. In addition, as noted above, numerous companies have as a result of our citations initiated a recall of violative products.

B. Prosecutions

In your report you indicate that prosecutions under the Act are necessary for a strong enforcement program. We agree. Not only are prosecutions contemplated by the Act, but the enforcement of the Act through criminal prosecutions supports and strengthens our other enforcement activities as well.

In December 1967 a Prosecutions and Imports Section was created in the Pesticides Regulation Division. This Section became sufficiently staffed in January 1968 so that work could be commenced on setting up procedures for the handling of prosecutions. We are currently reviewing all cases in the recent past to determine whether criminal prosecution should be recommended.

On page 19-23 of your report, you refer to numerous alleged violations of the Act on the part of a shipper of disinfectants. We are aware of the past history of this company and a review of all actions relative to this company during the past year became the first order of business of the Prosecutions and Imports Section. A prosecution file relating to this company has been prepared and is currently awaiting review.

GAO note: Agency attachment not included in this report.

The present operating guidelines for the referral of cases for prosecution are that we will forward for prosecution cases where (1) the evidence indicates that the violation was willful, (2) the violation is of a serious nature (e.g., significant deficiency of active ingredient or contamination) and is the result of apparent gross negligence, or (3) the company has engaged in repeated violations.

III. Related Enforcement Activities

During the past year significant changes have been made in our enforcement activities in other areas. Although certain of these areas were not specifically referred to in your report, our enforcement activities in these areas are directly related to the removal of violative products from channels of trade. For this reason, we will refer to them briefly.

A. Imports

It is the responsibility of this Department and the Department of the Treasury to jointly regulate the importation of all economic poisons and devices. Effective regulation of imported pesticides and pesticidal devices is essential if we are to prevent violative imported products from reaching the ultimate consumer. During the past year, we have made a complete review of our import program and have initiated procedures designed to more effectively regulate the importation of pesticides into this country. Attachment 4 [See GAO note.] sets forth our present policy and procedures with respect to imports.

B. Cooperation with States

We believe that the removal of violative products from the market can be more effectively accomplished if close liaison exists between the Department and State regulatory agencies. The Act contemplates that the Department will cooperate with State regulatory agencies in carrying out the provisions of the Act. While close cooperation has existed between the Division and State agencies in the registration of products, there has been no practical or effective cooperative program in the area of enforcement. During the past year, the Pesticides Regulation Division held four regional conferences to which State regulatory officials were invited. One of the primary purposes of these conferences was to discuss enforcement problems with State officials, and to explore the areas in which there could be effective cooperation between the Federal and State agencies.

As a result of our meetings with State officials, we intend during the next fiscal year to make certain recommendations to the States which, if agreeable to any of the State agencies, will, in our opinion, improve the efficiency of Federal--State regulatory activity in the pesticide chemical field. These recommendations will involve (1) the referral by Pesticides Regulation Division to the States of cases involving apparent violations of both the Federal and State acts, but where specific evidence establishing Federal jurisdiction is lacking, (2) the direct referral to our

GAO note: Agency attachment not included in this report.

Supervisory Inspectors of State analytical reports, (3) the establishment of a procedure whereby States are informed of registration cancellations involving potentially hazardous products, and (4) the establishment of a procedure whereby States are informed of recalls initiated by Pesticides Regulation Division.

IV. Legislation

In your report you stated that proposed legislation, if enacted and properly implemented, would achieve generally more effective regulation of pesticides. As you know, legislation of the type referred to in your report was drafted by the Department in 1965 and was transmitted to the Congress in August of that year. The proposed legislation was introduced in Congress in 1965 and again in 1967. It is presently pending in the Congress.

V. Notices of Judgment

You noted in your report that notices of judgment under the Federal Insecticide, Fungicide, and Rodenticide Act had not been published since November 1964 and recommended that procedures involving the frequency of future publications of notices of judgment be established and implemented. You also noted that action to resume the publications has been taken.

Work on a new format for notices of judgment was commenced in June of 1967. To date 100 notices have been prepared. There are presently pending 375 cases which require notices. Due to the limited staff in the Enforcement Branch, it is impossible to state when this backlog will be eliminated. However, it is anticipated that we will be current in our publication of notices by the end of this year. Thereafter, we intend to publish notices of judgment at intervals of not more than six months.

Summary

Our primary enforcement objective under the Federal Insecticide, Fungicide, and Rodenticide Act is to uniformly enforce all the provisions of the Act through all means available to us under the statute. Our yardsticks for measuring enforcement activity are whether such activity is within the framework established by the Congress, and whether the particular enforcement action is best suited to accomplish the purposes of the Act.

It is our belief that the effectiveness of an enforcement program cannot be judged solely upon the basis of numbers, i.e., numbers of citations, seizures, and prosecutions. An effective enforcement program should not be, merely, punitive in nature, but should emphasize corrective action. Its principal aim should be compliance, not punishment.

Ideally, we should expect an effective enforcement program to reduce violations under the Act. We believe that the best means to accomplish this end are:

1. A strong enforcement program in which we firmly, but fairly, enforce the provisions of the Act. Awareness on the part of industry that the Department can and will monitor industry activities and that strong enforcement action will be taken where warranted, should, by itself, go a long way to achieving compliance with the Act's provisions.

2. Cooperation by industry. We emphasize that industry also has an enforcement responsibility, and that our enforcement program under the Act includes cooperative industry action in any problem area.

Sincerely yours,

R. J. Anderson
Acting Administrator

Enclosures 5 [See GAO note.]

GAO note: Agency enclosures not included in this report.

REPORT TO THE CONGRESS

Need To Resolve Questions Of Safety Involving Certain Registered Uses Of Lindane Pesticide Pellets B-133192

Agricultural Research Service
Department of Agriculture

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

FEB. 20, 1969

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-133192

To the President of the Senate
and the Speaker of the House of Representatives

This is our report on the need for the Agricultural Research Service of the Department of Agriculture to resolve questions of safety involving certain registered uses of lindane pesticide pellets.

Copies of this report are also being sent to the Director, Bureau of the Budget, and to the Secretary of Agriculture.

Elmer B. Staats
Comptroller General
of the United States

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

NEED TO RESOLVE QUESTIONS OF SAFETY INVOLVING CERTAIN REGISTERED USES OF LINDANE PESTICIDE PELLETS
Agricultural Research Service
Department of Agriculture B-133192

DIGEST

WHY THE REVIEW WAS MADE

The Federal Insecticide, Fungicide, and Rodenticide Act requires the registration of all pesticide products with the Department of Agriculture before these products can be shipped across State lines. The Agricultural Research Service (ARS) of the Department is responsible for administering the law.

Before ARS registers a pesticide, the manufacturer must provide scientific evidence proving that its product is effective against particular pests. The manufacturer also must demonstrate that the product is safe when used as directed.

ARS has registered about 100 products using the chemical lindane in pellet form to kill certain crawling and flying insects--roaches, silverfish, flies, mosquitos, gnats, etc. About half these products are registered for use in continuously operating vaporizers in commercial and industrial establishments.

The General Accounting Office (GAO) reviewed ARS policy of registering lindane pellets, because information obtained in a previous review of ARS regulatory activities indicated that problems existed in registering such products.

FINDINGS AND CONCLUSIONS

ARS registers lindane pellets for use in continuously vaporizing devices in commercial and industrial establishments--such as restaurants and other food handling businesses--even though the Public Health Service, Food and Drug Administration and other Federal, State and private organizations have long opposed this use.

These organizations have questioned the adequacy of the scientific data available to prove that continuous vaporization of lindane pellets is safe in certain commercial and industrial establishments.

ARS has not resolved this question of safety as raised by these organizations. Nor has ARS taken action to restrict or disapprove the use of lindane pellets in vaporizers in certain commercial and industrial establishments.

GAO believes that this situation emphasizes the need for ARS to act to resolve this question of safety to human health.

Tear Sheet

The comments on this report by the American Medical Association, The President's Science Advisory Committee, and the Department of Health, Education, and Welfare are included as appendixes II, III, and IV, respectively.

RECOMMENDATIONS OR SUGGESTIONS

The Secretary of Agriculture should review the ARS policy of registering lindane pellets, with a view toward resolving the question of safety to human health.

AGENCY ACTIONS

ARS plans to meet with

--representatives of other Federal agencies to determine steps necessary to resolve lindane problems, and

--medical experts who serve as collaborators to ARS for advice and counsel on the use of pesticides. (See p. 20.)

ISSUES FOR FURTHER CONSIDERATION

None.

LEGISLATIVE PROPOSALS

None.

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

NEED TO RESOLVE QUESTIONS OF SAFETY INVOLVING CERTAIN REGISTERED USES OF LINDANE PESTICIDE PELLETS
Agricultural Research Service
Department of Agriculture B-133192

D I G E S T

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--medical experts who serve as collaborators to ARS for advice and counsel on the use of pesticides. (See p. 20.)

ISSUES FOR FURTHER CONSIDERATION

None.

LEGISLATIVE PROPOSALS

None.

INTRODUCTION

The General Accounting Office has examined into the policy of the Agricultural Research Service, Department of Agriculture, of registering, for use in vaporizing devices, pesticide pellets containing the chemical lindane. Our review was made pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67) and was directed primarily to an inquiry into the registration of lindane pellets rather than to the general matter of product registrations or the administration of other activities of the Department or ARS that involve pesticides.

Our review of registration matters relating to lindane pellets was performed because, during a previous review of a Department activity involving pesticides (see General Accounting Office report to the Congress on Need To Improve Regulatory Enforcement Procedures Involving Pesticides, Agricultural Research Service, Department of Agriculture, dated September 10, 1968, B-133192), we noted that certain ARS enforcement problems were associated with the registration of lindane pellets. The scope of our review is described on page 23.

BACKGROUND

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947 (7 U.S.C. 135) provides the basic legal authority for regulating the interstate marketing of pesticides to protect the interests of both the user of pesticides and the consumer of products protected by pesticides. The Secretary of Agriculture is responsible for administering and enforcing the FIFRA. Authority for implementing the FIFRA is delegated to the Pesticides Regulation Division (PRD) of ARS.

The FIFRA provides that every commercial pesticide formulation must be registered with the Department of Agriculture before it can be sold in interstate commerce. According to the Department, over 60,000 pesticide formulations based on more than 900 individual chemical compounds have been registered during the last 2 decades. Registration is

valid for a period of 5 years, after which registrants are required by ARS to reregister products. Before registration is granted, a pesticide must meet tests proving its claimed effectiveness against a particular pest or pests and demonstrating its safety when used as directed.

Federal regulations (7 CFR 362) provide that a registration may be canceled at any time if it appears that a pesticide does not warrant the proposed claims for it or does not otherwise comply with the act. In accordance with section 4.c. of the FIFRA, a cancellation of registration is effective 30 days after the registrant has been notified of the action unless within such time the registrant (1) makes the necessary corrections, (2) files a petition requesting that the matter be referred to an advisory committee selected by the National Academy of Sciences,[1] or (3) files objections and requests a public hearing.

Under formal agreement with the Department of Agriculture, the Departments of Health, Education, and Welfare (HEW) and Interior review the applications for pesticide registrations to ensure reflection of health and conservation viewpoints, as well as submit advisory opinions to the Department of Agriculture for its use in making registration decisions.

In accordance with the agreements, the Public Health Service (PHS) of HEW reviews proposed pesticide container labels to make sure that (1) caution statements are clear and appropriate in terms of what is known about the toxicity of the formulation ingredients, (2) products will not create a human hazard under the conditions of use, (3) antidote statements are complete and accurate for the chemicals used and reflect up-to-date medical information, and (4) proper chemical names are listed and have trade names correctly indexed to them.

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[1]The National Academy of Sciences is a nonprofit quasi-official agency of the Federal Government consisting of scientists and engineers who, when called upon by a Government agency, investigate, examine, experiment, and report on any subject of science or art.

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In addition other public and private organizations--such as the Food and Drug Administration (FDA) of HEW and the American Medical Association--have interests involving pesticides that are registered for use in this country.

As part of the registration requirements, the Department of Agriculture regulates the content of labels for pesticide products under the provisions of section 4 of the act. Federal regulations require that warning and cautionary statements be displayed on the labels of pesticides. The nature and scope of the safety claim on the label must conform to proven facts and all labels must bear registration numbers indicating that the product has been accepted by the Department as adequate to permit both safe and effective use when container directions are followed.

Section 2.z.(f) of the FIFRA states that products registered under the act are misbranded if any word, statement, or other information required by or under authority of the act appears on the label or labeling and is not (1) prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and (2) in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

According to ARS policy (Registration Policy for Lindane Vaporizers, dated October 17, 1961), lindane pellets, which emit toxic vapors from vaporizing devices, are accepted for registration by ARS on the basis that the pellets will be used in either of two particular types of devices. One is a continuously operating thermally regulated type of vaporizer which has been accepted for use in commercial and industrial establishments. The other type of equipment (fumigator), which is intended to vaporize a fixed amount of lindane within a short period of time under rigidly prescribed conditions, is acceptable for intermittent use in the home.

The policy also specifies that the directions for using the continuously operating type of vaporizer in commercial and industrial establishments should warn against contaminating food or food handling surfaces. Lindane pellets used

in the vaporizing devices have been accepted for registration by ARS since the early 1950's.

According to ARS, there are about 100 registrations of lindane pellets, approximately 50 of which provide for use of the pellets in continuously operating vaporizers in commercial and industrial establishments. Estimates of commercial and governmental sources indicate that millions of the vaporizers have been sold. The use of these products is intended for killing certain crawling and flying insects, such as roaches, silverfish, flies, mosquitos, and gnats.

Because of general public interest in the subject of pesticides, the President of the United States approved for publication, on May 15, 1963, a report containing the recommendations of his Science Advisory Committee on the use of pesticides. Government agencies were directed by the President to implement the recommendations of the committee, including matters for which the Department of Agriculture was responsible. Similarly, in November 1965, a report of the President's Science Advisory Committee on restoring the quality of our environment was published containing recommendations on pesticides for the consideration of the Department of Agriculture.

The principal officials of the Department of Agriculture responsible for matters involving the registration of lindane pellets are listed in appendix I to this report.

FINDINGS AND RECOMMENDATION

NEED TO RESOLVE QUESTIONS OF SAFETY INVOLVING CERTAIN REGISTERED USES OF LINDANE PESTICIDE PELLETS

On the basis of our review, we believe that there is a need for ARS to resolve questions of safety involving certain uses by the public of pesticide pellets containing the chemical lindane.

We found that ARS registers lindane pellets for use in vaporizing devices on a continuous basis in certain commercial and industrial establishments--such as restaurants and other food handling establishments--even though there has been long-term opposition to this practice by PHS and FDA as well as other Federal, State and private organizations.

Our review showed that the controversy associated with the use of the pellets stems from varying conclusions as to the adequacy of the scientific data that is available to prove that the continuous vaporization of lindane pellets in certain commercial and industrial establishments is safe.

The President's Science Advisory Committee Report on pesticides recommended continuing review of pesticide uses and, after hazard evaluation, restriction or disapproval for use on a basis of "reasonable doubt" of safety. On May 15, 1963, responsible Federal agencies, including ARS, were requested by the President of the United States to implement the recommendations contained in the report.

We have noted that ARS has not resolved questions of safety raised by other Federal agencies and by State and private organizations, nor has it taken action to restrict or disapprove the use of lindane pellets in vaporizers in certain commercial and industrial establishments since the products were first registered with the agency in the early 1950's.

We believe that the very existence of differences of opinion by various interested organizations emphasizes the

need for ARS to take action to resolve the differences. The details of our findings are discussed below.

Early information indicated that adequacy of scientific data on safety of using lindane vaporizers was questionable

According to ARS the initial registration of lindane pellets for use in continuously operating vaporizing devices in commercial and industrial establishments was accepted after PHS and FDA concurred with the adequacy of the data that was available to ARS in 1950 to support the safe use of such products.

Our review showed that, soon after the initial registrations of lindane pellets for use on a continuous basis in commercial and industrial establishments, some firms attempted to market the pellets for such use in the home. As a result ARS requested the formal opinion of the Interdepartmental Committee on Pest Control (ICPC), composed of representatives of the Departments of Agriculture, Interior, and Defense and the Federal Security Agency,[1] as to the conditions under which the lindane vaporizers could safely be used. On September 21, 1951, the ICPC issued the following statement with respect to the health hazards of thermal generators (vaporizers) used for the control of flying insects:

> "It is the considered opinion of the Interdepartmental Committee on Pest Control that there are at present no data to indicate that the use of thermal generators dispensing only lindane, DDT, or mixtures of the two, for the control of flying insects is unsafe when the following restrictions are enforced:
>
> 1. The insecticide shall be released at the rate not to exceed 1 gram per 15,000 cubic feet per 24 hours.
>
> 2. Installation shall be made only in commercial or industrial premises, mess halls, and

[1]Predecessor to HEW.

similar locations where human exposure will be on a working day basis - not continuous.

3. The devices should not be used in homes or sleeping quarters.

4. Devices shall be so constructed that output in excess of that recommended is impossible. Fuses to protect against overloading and high temperatures, and a pilot light to indicate whether or not the unit is operating should be 'built-in' features.

5. Units should be mounted above head height and 3 feet or more from the ceiling.

6. Installation shall be such that any material which might condense on nearby equipment, walls, or ceiling cannot be dislodged and fall into or otherwise contaminate food."

According to ARS this statement became the basis on which applications for registration of lindane pellets were accepted by the agency for continuous use only in commercial and industrial establishments.

The following year, on October 22, 1952, the ICPC, after considering additional data, revised its original statement on lindane vaporizers to include the following:

"Unless it can be demonstrated that contamination does not occur, the Committee recommends against the use of insecticide vaporizers in rooms or areas where food is served, processed or stored."

According to ARS the ICPC revised its statement because experimental work had shown that prolonged exposure of certain foods to lindane vapors resulted in absorption of lindane from the air and caused apprehension as to possible contamination of foods in the practical use of continuous-use lindane vaporizers. We found, however, that the ARS registration policy with respect to continuous-use lindane vaporizers was not changed regardless of the issuance of the revised statement.

Our review showed that, since September 1951, various government agencies and private interests have expressed concern over the lack of scientific data to support the safety of using lindance vaporizers under certain conditions. We found that, in October 1951, the Committee on Pesticides, American Medical Association (AMA), reported in the "Journal of the American Medical Association" that pharmacological findings on lindane were not consistent and that only the broadest generalities concerning susceptibility of various animal species to lindane were possible. Also, the report stated that little precise information has been recorded in medical literature on the inhalation effects of lindane.

Subsequent to the issuance of the revised statement of the ICPC, many State and local authorities imposed various restrictions on lindane vaporizers. The Committee on Pesticides, AMA, reported on July 25, 1953, that at least 14 States and 35 municipalities had adopted measures to control the installation, sale, or use of lindane vaporizers and that other States and local groups had invoked existing provisions of their food laws and sanitary codes for similar purposes.

We noted also that in November 1952, the Department of Public Health of one of our most populous States passed a resolution which "urgently recommended" that lindane vaporizers not be used in closed spaces where people sleep or work or where unpackaged food is exposed. The resolution stated that, at that time, adequate technical information was not available as to the toxicity of lindane, its rate of absorption by human lungs and food, and the range of concentration of lindane in air that might be expected to result from the continuous evaporation of lindane in a room, at any given rate.

As early as June 30, 1953, the Secretary of HEW, in a letter to the Chairman, Select Committee on Small Business, House of Representatives, questioned the safety of certain uses of the lindane vaporizers. The Secretary stated that PHS and FDA had made a joint investigation of the toxicology of lindane vapor and commented as follows:

"The research data available at present are insufficient for a complete appraisal of the effect of lindane vapor on humans. Those listed data which are available relate almost entirely to acute toxic effects. The long range or chronic effects of lindane vapor on humans are unknown. Inasmuch as data furnished from both * * * [a company] and Public Health Service studies show that lindane continues to be released into the air for some weeks after a single * * * [vaporizer] fumigation, we believe that exceptional caution in the use of lindane is in the public interest until there is scientific information sufficient to appraise its long term effects.

"The Interdepartmental Committee's release of March 27, 1953, emphasized the hazard of possible misuse under the uncontrollable conditions of home application. It is apparent now from review of the evidence submitted herewith that an equally serious concern is the unanswered question as to health hazards of long continued exposure to the low concentrations resulting from 'proper' use of vaporized lindane.

"It is certainly not the intent of this Department, nor within its authority, to ban the use of lindane in living quarters. Lindane is acknowledged to be a highly toxic compound. Although there probably are conditions under which it may be safely used as an insecticide, in our judgment the technical data are not yet sufficient to assure the safety of human exposure to low concentrations over long periods of time. The position of this Department is that lindane vaporizers (continuous or as fumigators) should not be used in areas where food is processed or stored, and that the public should be cautioned about the inherent dangers in general household application. This position will guide the regulatory activities of the Food and Drug Administration and the cooperative activities of the Public Health Service with State health officials. We are informing the

Department of Agriculture and the Federal Trade Commission of our position."

On August 3, 1953, a copy of this letter was transmitted to ARS.

Thus, on the basis of information available to ARS soon after the initial registrations of lindane pellets, it is our view that questions as to the adequacy of the data to support the safety of certain uses of the pellets were being and could continue to be raised by other interested organizations.

Questions as to adequacy of data to support certain uses of vaporizers have not been resolved

Our review showed that since 1953 various organizations have continued to question the safety of certain uses of lindane vaporizers and that the scientific data available has not been adequate to resolve the differences of opinion.

Both PHS and FDA have continued to oppose the use of continuously operating lindane vaporizers in food handling establishments and/or places of work. In a letter to the Director, Pesticides Regulation Branch,[1] ARS, dated December 1, 1959, the Assistant to the Director, Bureau of Biological and Physical Sciences, FDA, stated the agency's view toward lindane vaporizers as follows:

> "Our position on lindane vaporizers (continuous or as fumigators) is that they should not be used in areas where food is processed or stored, that the public should be cautioned against the inherent dangers of general household application and that inhalation of the vapor should be avoided."

Our review showed also that the Bureau of State Services, Environmental Health, PHS, appointed an Ad Hoc Committee to review the use of pesticide vaporizing devices. The Committee, which met on November 19, 1965, was asked to review the available data on the toxicology and usage pattern of the devices and to review all pertinent aspects of the problem from the standpoint of human health considerations. In its report on the meeting, the Committee expressed unanimous opposition to the use of lindane vaporizers. We noted that, during the meeting, members of the Committee had stated that, in connection with the use of lindane vaporizers (1) there was documentation of harm caused by these devices and (2) the questions of safety raised by the Committee on Pesticides, AMA, 15 years ago were still not answered.

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[1]Presently Pesticides Regulation Division (PRD), ARS

On September 22, 1966, the Surgeon General, PHS, transmitted a copy of the Ad Hoc Committee's report to the Deputy Administrator Regulatory and Control, ARS, and endorsed consideration of pesticide vaporizing devices by the National Research Council, National Academy of Sciences.

In accordance with the Interdepartmental Agreement between the Secretaries of Agriculture, Interior, and HEW, dated 1964, ARS furnishes PHS with applications for registration for review and comment. In connection with such reviews, PHS has objected to those applications for registrations of lindane pellets that provide for continuous vaporization in food handling establishments and places of work. We noted, however, that such applications have been subsequently accepted for registration by ARS.

The ARS registration policy for lindane pellets in vaporizers permits the continuous use of such products in restaurants and other food handling establishments although it requires that the labeling of the products bear cautionary statements against contaminating food or food handling surfaces.

For example, in February and April 1967, a company submitted labeling and revised labeling to ARS in connection with an application for registering lindane pellets for continuous-use vaporizers. We found that, on April 28, 1967, ARS referred the application for registration to PHS for comments with respect to the safety of the products. On May 5, 1967, PHS informed ARS that it could not recommend registration of the product because the design and usage pattern provided for continous vaporization of lindane in food handling establishments and places of work. We noted, however, that ARS accepted the lindane pellets for registration on a continuous-use basis on June 19, 1967.

On July 5, 1967, an ARS inspector submitted a sample of the firm's labeling for lindane pellets for use in the continuous-use vaporizer to the Acting Head, Inspection Services and Accident Investigation, PRD, ARS, for the purpose of determining whether such labeling was acceptable to ARS. The inspector pointed out that there appeared to be a contradiction in the labeling in that one side of the

pellet box made claims for use of the vaporizer in commercial establishments, restaurants, bars, warehouses, stores, offices, lobby rooms, and storage rooms, and the other side of the box contained warnings against inhalation and contamination of feed and foodstuffs.

The inspector asked how it was possible to use the device in commercial establishments and yet heed the warnings. The inspector pointed out that it appeared that such devices in continuous operation in occupied restaurants, bars, stores, offices, and lobby rooms would be just as hazardous as one in continuous use in a home--use for which ARS does not register lindane pellets in vaporizing devices.

On August 21, 1967, the Acting Head, Inspection Services and Accident Investigation, PRD, ARS, informed the field inspector that the labeling he had submitted was substantially the same as that which ARS had accepted for registration in June 1967.

In connection with the continuous use of such products in food handling establishments, the Chief, Laboratory Branch, acting for the Director, Technical Services Division, Consumer and Marketing Service (C&MS)--the organizational entity of the Department of Agriculture charged with responsibility for carrying out Federal laws and regulations relating to the wholesomeness of meat and poultry being processed in this country--informed us that C&MS did not approve of the use of continuously operating lindane vaporizers where meat or poultry would be exposed to the vapor. This official informed us also that, generally, it was C&MS policy to allow the use of pesticides in establishments if it could be shown that there would never be any contamination of food material. The official informed us further that in the case of continuously operating lindane vaporizers, as well as similar vapor or spray devices, there would always be some contamination of exposed food materials.

An article published in the July 1967 issue of the AMA's "Archives of Environmental Health" points out that since 1954 exposure to lindane has been implicated directly or circumstantially in cases of serious bone marrow failure

but that there has been no method developed yet for proving a cause and effect relationship between a chemical exposure and bone marrow failure in the individual case which may occur and that no follow-up investigation has been conducted in such cases.

The article states that millions of lindane vaporizers have been sold over the last 15 years and points out that regardless of whether or not a cause and effect relationship exists, practical and flexible administrative provisions should exist so that (1) the burden of proof involving a fatal disease should not rest upon the public and (2) further exposure of the public to a chemical can be curtailed until research can satisfactorily answer the health questions which have arisen.

Our review showed that the scientific studies performed on lindane vaporizers had not resolved the differences of opinion between ARS and other organizations as to the safety of certain uses of the equipment. According to ARS files, various types of studies have been performed by universities, Federal agencies, and private individuals on lindane vaporization. We found, however, that the studies often produced conflicting conclusions as to the safety of using lindane vaporizers.

For example, in August 1952 a firm submitted a report of tests on its vaporizer. According to the firm the report illustrated that lindane vapor within prescribed limits could safely be used in restaurants or food-processing establishments. In June 1953 an FDA official reported that an FDA study of the same firm's vaporizer under other limits revealed that:

> "Contamination of foods and surfaces does occur when these substances are exposed to lindane vapors.
>
> "Various types of foods and surfaces display considerable differences in adsorptive capacities to identical air concentrations of lindane.

"The amount of lindane adsorbed by foods and surfaces is related to air concentration and duration of exposure.

"Protection of foods and surfaces is not achieved by covering or packaging with the common wrapping materials except metal.

"The rate of disappearance of lindane from contaminated substances is neither constant nor uniform."

In connection with the conflict on the scientific data relating to the safety of lindane vaporizers, we noted that the report of the President's Science Advisory Committee, entitled "Use of Pesticides," dated May 15, 1963, recommended that the toxicity data relating to man that registrations and tolerances are based on be more complete and of higher quality. Also, the report recommended that ARS provide on a continuing basis for:

"Review of pesticide uses and, after hazard evaluation, restriction or disapproval for use on a basis of 'reasonable doubt' of safety."

Thus, the May 1963 recommendations established that registrations were to be based on more complete data of higher quality, while questions as to the adequacy of data to support certain registered uses of lindane pellets were continuing to be raised by other interested organizations. In our opinion ARS has not implemented these recommendations with respect to certain registered uses of lindane pellets.

ARS basis for continuing policy of registering certain uses of lindane pellets appears questionable

According to ARS approximately 50 lindane pellet products for use in continuously operating vaporizers were registered with the agency as of June 1968. Moreover, the Assistant Director for Registration, PRD, ARS, stated that the agency would continue to register and reregister lindane pellets for use in continuously operating vaporizers in food handling establishments and places of work, on the basis that such uses had already been accepted for other registrants of lindane pellets and that refusal to accept such uses would be discriminatory to the applicant. The Assistant Director for Registration stated also that, because lindane vaporizers had previously been accepted by ARS for use in food handling establishments and places of work, the burden of proof was now on the agency to show that such use was not safe.

The Assistant Director informed us, however, that ARS had never (1) undertaken adequate tests to prove that lindane pellets registered with ARS were safe or (2) referred questions as to the safety of the products to the National Academy of Sciences.

Our review showed that, in regulating the continuance of registrations as well as providing limitations on registrations, the Code of Federal Regulations (7 CFR 362.10) states that:

> "If a registrant desires to continue the registration in effect, he shall notify the Pesticides Regulation Division in writing and it shall be continued in effect under the same terms as the original registration: Provided, however, That if, on the basis of information available at the time, it appears that the product or its labeling fails to comply with the Act, the registrant shall be so notified and afforded the opportunity to make the necessary corrections. If the corrections are not made, registration will be cancelled as provided in section 4.c. of the Act.

> "The Director may refuse to register any economic poison or any specific use thereof if, in his opinion, directions and warnings cannot be written which will prevent injury to the general public when the product is used in accordance with warnings and directions or in accordance with commonly recognized practices. If, however, such an economic poison is proposed for certain acceptable uses, the Director may require the label to bear a warning against specific unacceptable uses such as in the home or home garden."

In accordance with section 4.c. of the FIFRA, cancellation of a registration is effective 30 days after the registrant is notified of the action unless within such time the registrant (1) makes the necessary corrections, (2) files a petition requesting that the matter be referred to an advisory committee selected by the National Academy of Sciences, or (3) files objections and requests a public hearing.

Also, we found that, in its report dated November 1965, the Environmental Pollution Panel of the President's Science Advisory Committee noted that the finding of new evidence that casts doubt on the validity of a registration and causes it to be reexamined was too frequently interpreted as a shifting to ARS of the burden of proof that registration was not valid, and that such an interpretation was contrary to that intended in the FIFRA.

The Panel recommended that, in all proceedings concerning the registration or reregistration of pesticides for agricultural use, the Department of Agriculture fully implement the principle that the burden of proof is deemed to fall on the registrant. Moreover, the Panel recommended that the Department require that reregistration of agricultural pesticides be conducted without prejudice from the approval of registration for the previous term.

Although we recognize that the Panel's concern was directed to agricultural pesticides, we believe that similar considerations should be afforded to any pesticide product that comes into intimate contact with humans, their food, or their environment. In any event, the position of

ARS regarding burden of proof appears to be contradictory to the recommendations of the Panel.

Conclusion

On the basis of our review, we believe that there is a need for ARS to resolve questions of safety involving certain uses by the public of pesticide pellets containing the chemical lindane.

We believe that the very existence of differences of opinion by various interested organizations as to the safety of the product emphasizes the need for ARS to resolve the differences.

Recommendation to the Secretary of Agriculture

In view of the questions raised by various organizations as to the safety of certain registered uses of lindane pellets, as well as the recommendations of the President's Science Advisory Committee as to reasonable doubt of safety and burden of proof, we recommend that a review be made of the ARS policy of registering the pellets, with a view toward resolving the differences of opinion as to the safe use of these products.

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The comments of AMA, the President's Science Advisory Committee, and the Departments of HEW and Agriculture on the matters discussed in this report are included as appendixes II, III, IV, and V, respectively. The comments of these organizations on specific information in the report have been recognized in the sections of the report that present the information. Comments of the Department of Agriculture on our recommendation are presented below.

By letter dated November 27, 1968, the Director of Science and Education, Department of Agriculture, in commenting on our recommendation, stated that:

"Information has recently come to our attention which indicates the need for a reevaluation of

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the safety of lindane in an uncontrolled environment. It has been shown that malnutrition greatly enhances the toxicity of lindane in laboratory animals. Significant residue levels have also been found in tissues of animals exposed to vaporized lindane. ARS is arranging a meeting with the departmental representatives responsible for carrying out the provisions of the Interagency Agreement to determine what steps should be taken in regard to the problem of lindane vaporizers. Also, a meeting is being scheduled with medical experts who serve as collaborators to the Pesticides Regulation Division for advice and counsel on matters dealing with the use of pesticides. The collaborators are: Bertram D. Dinman, M.D., D.Sc., Professor of Industrial Health, University of Michigan, Ann Arbor; Victor A. Drill, M.D., Ph.D., Director of Biological Research, G. D. Searle and Company, Chicago; and Ted A. Loomis, M.D., Ph.D., Professor of Pharmacology and Toxicology, University of Washington, Seattle."

The information on malnutrition referred to by the Director is contained in an article on lindane toxicity and protein deficient diet that was published in the August 1968 issue of AMA's "Archives of Environmental Health." In summarizing the information presented in the article, the authors of the article concluded that the results of their work suggested the possibility that lindane should be used as an insecticide with caution in countries where diet is deficient in protein.

The information on residue levels referred to by the Director is contained in an article on the retention of vaporized lindane by plants and animals that was published in the May-June 1967 issue of the "Journal of Agricultural and Food Chemistry." In presenting the conclusions to this article, the authors stated that, as is the case with pesticides in general, applied in any manner, no absolute statement could be made with respect to safe usage, and, therefore, extreme caution must be exercised when using thermal vaporizers around living organisms other than the target insects.

In our opinion the meetings being planned by ARS are appropriate to taking action to resolve questions as to the safety of certain registered uses of lindane pellets and should be helpful in identifying additional actions that may be needed.

SCOPE OF REVIEW

Our review included (1) the history that gave rise to the ARS policy of registering lindane pellets for use in vaporizing devices, (2) ARS product registration, correspondence, and enforcement files relating to lindane pellets and vaporizers, and (3) certain information of the Food and Drug Administration and Public Health Service, Department of Health, Education, and Welfare, and of other organizations related to the use of lindane in vaporizing devices. Our review was performed principally in the offices of the Pesticides Regulation Division of ARS at Washington, D.C.

APPENDIXES

APPENDIX I

PRINCIPAL OFFICIALS OF

THE DEPARTMENT OF AGRICULTURE

RESPONSIBLE FOR THE ADMINISTRATION

OF ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
DEPARTMENT OF AGRICULTURE		
SECRETARY OF AGRICULTURE:		
Orville L. Freeman	Jan. 1961	Jan. 1969
Clifford M. Hardin	Jan. 1969	Present
DIRECTOR OF SCIENCE AND EDUCATION:		
Nyle C. Brady	Dec. 1963	Aug. 1965
George L. Mehren	Sept. 1965	June 1968
Ned D. Bayley	July 1968	Present
AGRICULTURAL RESEARCH SERVICE		
ADMINISTRATOR:		
Byron T. Shaw	June 1954	Mar. 1965
George W. Irving, Jr.	Mar. 1965	Present
DEPUTY ADMINISTRATOR REGULATORY AND CONTROL:		
Robert J. Anderson	Mar. 1963	Nov. 1966
Francis J. Mulhern (acting)	Jan. 1967	May 1967
Francis J. Mulhern	May 1967	Present
DIRECTOR, PESTICIDES REGULATION DIVISION:		
Justus C. Ward	Nov. 1961	June 1966
Harry W. Hays	July 1966	Present

APPENDIX II

AMERICAN MEDICAL ASSOCIATION
535 NORTH DEARBORN STREET • CHICAGO, ILLINOIS 60610 • PHONE (312) 527-1500 • TWX 910-221-0300

DIVISION OF SCIENTIFIC ACTIVITIES
DEPARTMENT OF OCCUPATIONAL HEALTH
HENRY F. HOWE, M.D.
Director

October 25, 1968

Mr. A. T. Samuelson
United States General Accounting Office
Civil Division
Washington, D.C. 20548

Dear Mr. Samuelson:

Henry F. Howe, M.D., has asked me to reply to your letter of October 11, 1968, addressed to John Adriani, M.D., concerning the draft of your proposed report to the Congress of the United States involving the uses of lindane pellets.

We cannot add any additional information other than that contained in your report. The cases of major blood dyscrasias implicating lindane reported to the AMA Registry on Blood Dyscrasias have been mentioned in the article by Irma West, M.D., "Lindane and Hematologic Reactions" published in the AMA Archives of Environmental Health, July 1967. You have made reference to this article in your report. It should be emphasized that no follow-up investigation has been conducted in these cases. These reports provide only circumstantial but not conclusive evidence of cause-effect relationship.

Sincerely,

Jerome T. Siedlecki

Jerome T. Siedlecki
Assistant Director

APPENDIX III

THE PRESIDENT'S SCIENCE ADVISORY COMMITTEE
EXECUTIVE OFFICE BUILDING
WASHINGTON, D.C. 20506

November 15, 1968

Dear Mr. Samuelson:

This is in response to your request for review and comment on the draft GAO report dealing with government policy on the uses of lindane pellets, particularly with regard to past reports of the President's Science Advisory Committee on pesticides in the environment.

In this regard, we would suggest a change in the wording of the last paragraph on page 9 of the draft to more precisely reflect the role of the President's Science Advisory Committee, as follows:

> "~~In accordance with the recommendations of~~ The President's Science Advisory Committee Report on pesticides, ~~ARS is required to continually~~ recommended continuing review of pesticide uses and, after hazard evaluation, restriction or disapproval for use on a basis of 'reasonable doubt' of safety. On May 15, 1963, responsible Federal agencies, including ARS, were requested by the President of the United States to implement the recommendations contained in the report."

We have no further comments to offer on the draft.

Sincerely yours,

David Beckler

David Beckler
Executive Officer

Honorable A. T. Samuelson
Director
U. S. General Accounting Office
Washington, D. C. 20548

APPENDIX IV

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CONSUMER PROTECTION AND ENVIRONMENTAL HEALTH SERVICE
WASHINGTON, D.C. 20204

OFFICE OF THE
ADMINISTRATOR

NOV 1 1968

Mr. Frederick K. Rabel
Assistant Director
U. S. General Accounting Office
Washington, D. C. 20548

Dear Mr. Rabel:

The draft document "Need to Resolve Questions of Policy Involving Certain Registered Uses of Lindane Pellets," has been reviewed as requested in your letter of October 15, 1968, to Assistant Secretary Lee.

The draft is substantially correct as reflected by a review of our files. However, on page 15, it appears that it would be in order for the report to state that in transmitting the Ad Hoc Committee report in 1966, the Surgeon General endorsed consideration of pesticide vaporizing devices by the National Research Council - National Academy of Sciences.

The most recent restatement of DHEW policy concerning the registration of lindane vaporizers was made to USDA on July 12, 1968, commenting on an application by the I K I Manufacturing Company, Edgerton, Wisconsin, to re-register lindane pellets.

The document presents a factual review of the present and past registration status of lindane pellets and the concern DHEW has continually expressed regarding the registered uses of pesticide vaporizers.

In our opinion, there is still need for the resolution of the questions concerning the safe use of these products.

Sincerely yours,

Charles C. Johnson, Jr.

Charles C. Johnson, Jr.
Administrator

APPENDIX V

DEPARTMENT OF AGRICULTURE
WASHINGTON, D.C. 20250

November 27 1968

Mr. A. T. Samuelson
Director
Civil Division
General Accounting Office
Washington, D.C. 20548

Dear Mr. Samuelson:

This is in response to your request for our comments on the draft of your proposed report to Congress entitled "Need to Resolve Questions of Policy Involving Certain Registered Uses of Lindane Pellets, Agricultural Research Service, Department of Agriculture."

The principal allegations in your report are (1) that information available to ARS soon after the initial registration of lindane pellets raised some doubt as to the adequacy of the data to support safety, and (2) that this matter still remains unresolved.

The Federal Insecticide, Fungicide, and Rodenticide Act requires that all economic poisons shipped in interstate commerce be registered with the Department of Agriculture and that they be effective and safe when used in accordance with the label directions and warnings. The data submitted with the application for lindane pellets showed that they were effective against a variety of insects and the amount emitted into the atmosphere was such that it would not be injurious to man or beneficial animals.

Those in ARS responsible for the administration of the Act have always been conscious of the potential health hazards of pesticides. Even before any formal agreements were established for consultation with other Government agencies, their informal advice was sought prior to the registration of pesticides which might be within their sphere of interest. Extensive use was also made of advice from the Interdepartmental Committee on Pest Control, composed of representatives of the Departments of Agriculture, Interior, Army, Navy, Air Force, and the Federal Security Agency (Public Health Service and Food and Drug Administration). We would like to summarize some of the early history relating to the acceptance of lindane in vaporizing devices.

In May of 1948, the Aerovap Corporation of England undertook to register vaporized DDT for fly control. The use was accepted following submission of data and upon the concurrence of Dr. Paul A. Neal of the National Institutes of Health. The following year, flies were found to be developing resistance to DDT and lindane was proposed as a substitute. The question of its hazards became of paramount importance and the industry was required to make extensive investigations to determine limitations under which it could be used. In June of 1950, the Public Health Service and the Food and Drug Administration were supplied with all available data and asked for comments. The Public Health Service gave the opinion that the exposure of persons on an 8-hour working day basis would not be injurious and toxicologists of the Food and Drug Administration stated that the possibility of any ill effects resulting from the breathing of air where a lindane charged controlled device was operating would be extremely remote. With this type of support, the continuous equipment was accepted for use in commercial and industrial locations and the label was required to carry the statement "Not for Home Use." In the fall of 1951, the Interdepartmental Committee on Pest Control issued a statement on the health hazards of thermogenerators used for control of flying insects. This statement outlined the pattern for registration acceptance and was used by the Public Health Service, the Food and Drug Administration, and Agriculture in replies to inquiries on vaporizers.

In 1952, a second statement was issued by the Interdepartmental Committee on Pest Control warning against contamination of food. Although there was evidence that excessive dosages or prolonged exposure of fatty foods might result in contamination, there was no evidence that the properly controlled vaporizers used in accordance with the registered directions would cause significant contamination.

The firm prohibition of continuous units for home use led segments of the industry in 1952 to search for acceptable methods for the use of lindane vaporization in the home. In May of that year, the so-called "one shot" fumigating device was submitted for registration. In this procedure, the maximum of 2 grams of lindane per 1500 cubic feet was to be vaporized in unoccupied space from which pets, birds, fish, and persons had been removed and in which all exposed food was to be tightly covered. Thorough airing of the space was also required before reoccupancy. This method was discussed with the Public Health Service and they agreed that such direction, if followed, would be adequate to safeguard the public. Accordingly, registration of this type of vaporizer was started.

Because of the apprehension of possible misuse of the home units, the Interdepartmental Committee on Pest Control issued a third statement in March of 1953, condemning home use because of the potentialities of misuse. This release was challenged immediately as being unfair to small business

since the industry contended that no evidence was available to indicate that anyone had been harmed by home use. Industry appealed to the Small Business Committee of the House of Representatives and questioned the right of a committee composed of Government people to issue such a release and it was withdrawn in April 1953.

A review of all available data on lindane toxicity and the potential hazards associated with its use in vaporizers indicated that extensive exposure of workers in lindane formulating and manufacturing plants had not resulted in any detectable injury. Long-term exposure of laboratory animals to vaporized lindane at the Kettering Laboratories in Cincinnati and in the entomology laboratories at the University of Massachusetts, showed no effects that were significantly different from control animals. Clinical reports on lindane gathered by the American Medical Association did not show any cases resulting from home fumigator exposure. It was concluded at that time that there was insufficient evidence to support any action on the part of ARS to cancel the registered products or to refuse additional registrations.

The President's Science Advisory Committee report on "Use of Pesticides," recommended that activities relating to pesticides be coordinated with the Department of Health, Education, and Welfare and the Department of the Interior. In 1964, an interagency agreement established formal procedures for evaluation of registration applications. Section 2(d) of the agreement states,"If one department concludes that the proposal should be rejected in whole or in part, this view shall be expressed in writing and shall be supported by the appropriate scientific evidence." While the U.S. Public Health Service has objected to the registration and reregistration of lindane vaporizer pellets, ARS felt that the evidence was not sufficiently well documented to support immediate action.

Information has recently come to our attention which indicates the need for a reevaluation of the safety of lindane in an uncontrolled environment. It has been shown that malnutrition greatly enhances the toxicity of lindane in laboratory animals. Significant residue levels have also been found in tissues of animals exposed to vaporized lindane. ARS is arranging a meeting with the departmental representatives responsible for carrying out the provisions of the Interagency Agreement to determine what steps should be taken in regard to the problem of lindane vaporizers. Also, a meeting is being scheduled with medical experts who serve as collaborators to the Pesticides Regulation Division for advice and counsel on matters

dealing with the use of pesticides. The collaborators are: Bertram D. Dinman, M.D., D.Sc., Professor of Industrial Health, University of Michigan, Ann Arbor; Victor A. Drill, M.D., Ph.D., Director of Biological Research, G. D. Searle and Company, Chicago; and Ted A. Loomis, M.D., Ph.D., Professor of Pharmacology and Toxicology, University of Washington, Seattle.

In determining what action is to be taken regarding registration, ARS relies first on the data submitted by the applicant in support of effectiveness and safety. In addition, reports of pesticides, both published and unpublished, are circulated among the scientific staff for review. Investigation of accidents provides valuable information in determining what additional studies may be required. Pesticide products are being reformulated each year and thus require amended labeling. If data become available to show that a product is ineffective or hazardous, the registrant is notified of the additional studies that would be required for continued registration.

The U.S. Department of Agriculture and the Department of Health, Education, and Welfare jointly requested the National Academy of Sciences-National Research Council to study the technical issues involved in the concepts of "no-residue" and "zero tolerance." The Academy recommended that these concepts be abandoned since they are administratively and scientifically untenable. On the basis of this recommendation, ARS is in the process of cancelling the registration of all pesticide uses for which tolerances or exemption from tolerances have not been established.

Before an orderly reduction in the use of persistent pesticides can be accomplished, there needs to be a review of the occurrence of pesticides in the environment, an evaluation of the significance of such residues in relation to the health of man and the safety of his food supply, the welfare of fish and wildlife, and the possible impact of substituting less persistent pesticides for more persistent ones now in use.

ARS has again requested the National Academy of Sciences - National Research Council to study the problems of persistent pesticides, including lindane, and will be guided by the findings of this study in developing policies relating to pesticide registration and use.

Sincerely yours,

Ned D. Bayley

Ned D. Bayley
Director of Science & Education

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APPENDIX 3.—TEXT OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

THE

FEDERAL INSECTICIDE, FUNGICIDE,

AND

RODENTICIDE ACT

(61 STAT. 163; 7 U. S. C. 135–135k)

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE
PESTICIDES REGULATION DIVISION

October 1, 1964

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

(7 U.S.C. 135-135k)

Approved June 25, 1947 (61 Stat. 163) as amended by the Nematocide, Plant Regulator, Defoliant, and Desiccant Amendment of 1959 (73 Stat. 286) as amended by the Act of March 29, 1961 (75 Stat. 18) and the Act of April 7, 1961 (75 Stat. 42) and the Act of May 12, 1964 (P.L. 88-305, 78 Stat. 190)

An Act to regulate the marketing of economic poisons and devices, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled.

TITLE

Section 1. This Act may be cited as the "Federal Insecticide, Fungicide, and Rodenticide Act."

DEFINITIONS

Sec. 2. For the purposes of this Act--

a. The term "economic poison" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any insects, rodents, nematodes, fungi, weeds, and other forms of plant or animal life or viruses, except viruses on or in living man or other animals, which the Secretary shall declare to be a pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant.

b. The term "device" means any instrument or contrivance intended for trapping, destroying, repelling, or mitigating insects or rodents or destroying, repelling, or mitigating fungi, nematodes,

or such other pests as may be designated by the Secretary, but not including equipment used for the application of economic poisons when sold separately therefrom.

c. The term "insecticide" means any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any insects which may be present in any environment whatsoever.

d. The term "fungicide" means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any fungi.

e. The term "rodenticide" means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating rodents or any other vertebrate animal which the Secretary shall declare to be a pest.

f. The term "herbicide" means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any weed.

g. The term "nematocide" means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating nematodes.

h. The term "plant regulator" means any substance or mixture of substances, intended through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of ornamental or crop plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments.

i. The term "defoliant" means any substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

j. The term "desiccant" means any substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

k. The term "nematode" means invertebrate animals of the phylum nemathelminthes and class nematoda, that is, unsegmented round worms with elongated, fusiform, or saclike bodies covered with cuticle, and inhabiting soil, water, plants or plant parts; may also be called nemas or eelworms.

l. The term "weed" means any plant which grows where not wanted.

m. The term "insect" means any of the numerous small invertebrate animals generally having the body more or less obviously segmented, for the most part belonging to the class insecta, comprising six-legged, usually winged forms, as, for example, beetles, bugs, bees, flies, and to other allied classes of arthropods whose members are wingless and usually have more than six legs, as, for example, spiders, mites, ticks, centipedes, and wood lice.

n. The term "fungi" means all non-chlorophyll-bearing thallophytes (that is, all non-chlorophyll-bearing plants of a lower order than mosses and liverworts) as, for example, rusts, smuts, mildews, molds, yeasts, and bacteria, except those on or in living man or other animals.

o. The term "ingredient statement" means either--

(1) a statement of the name and percentage of each active ingredient, together with the total percentage of the inert ingredients, in the economic poison; or

(2) a statement of the name of each active ingredient, together with the name of each and total percentage of the inert ingredients, if any there be, in the economic poison (except option 1 shall apply if the preparation is highly toxic to man, determined as provided in section 6 of this Act); and, in addition to (1) or (2) in case the economic poison contains

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arsenic in any form, a statement of the percentages of total and water soluble arsenic, each calculated as elemental arsenic.

p. The term "active ingredient" means--

(1) in the case of an economic poison other than a plant regulator, defoliant or desiccant, an ingredient which will prevent, destroy, repel, or mitigate insects, nematodes, fungi, rodents, weeds, or other pests;
(2) in the case of a plant regulator, an ingredient which, through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the produce thereof;
(3) in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant;
(4) in the case of a desiccant, an ingredient which will artificially accelerate the drying of plant tissue.

q. The term "inert ingredient" means an ingredient which is not active.

r. The term "antidote" means a practical immediate treatment in case of poisoning and includes first-aid treatment.

s. The term "person" means any individual, partnership, association, corporation or any organized group of persons whether incorporated or not.

t. The term "Territory" means any Territory or possession of the United States, excluding the Canal Zone.

u. The term "Secretary" means the Secretary of Agriculture.

v. The term "registrant" means the person registering any economic poison pursuant to the provisions of this Act.

w. The term "label" means the written, printed, or graphic matter on, or attached to, the economic poison or device or the immediate container thereof, and the outside container or wrapper of the retail package, if any there be, of the economic poison or device.

x. The term "labeling" means all labels and other written, printed, or graphic matter--

(1) upon the economic poison or device or any of its containers or wrappers;
(2) accompanying the economic poison or device at any time;
(3) to which reference is made on the label or in literature accompanying the economic poison or device, except to current official publications of the United States Department of Agriculture and Interior, the United States Public Health Service, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of economic poisons.

y. The term "adulterated" shall apply to any economic poison if its strength or purity falls below the professed standard of quality as expressed on its labeling or under which it is sold, or if any substance has been substituted wholly or in part for the article, or if any valuable constituent of the article has been wholly or in part abstracted.

z. The term "misbranded" shall apply--

(1) to any economic poison or device if its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;
(2) to any economic poison--
(a) if it is an imitation of or is offered for sale under the name of another economic poison;

(b) if its labeling bears any reference to registration under this Act other than the registration number assigned to the economic poison;

(c) if the labeling accompanying it does not contain directions for use which are necessary and if complied with adequate for the protection of the public;

(d) if the label does not contain a warning or caution statement which may be necessary and if complied with adequate to prevent injury to living man and other vertebrate animals, vegetation, and useful invertebrate animals;

(e) if the label does not bear an ingredient statement on that part of the immediate container and on the outside container or wrapper, if there be one, through which the ingredient statement on the immediate container cannot be clearly read, of the retail package which is presented or displayed under customary conditions of purchase: Provided, That the Secretary may permit the ingredient statement to appear prominently on some other part of the container, if the size or form of the container makes it impracticable to place it on the part of the retail package which is presented or displayed under customary conditions of purchase;

(f) if any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(g) if in the case of an insecticide, nematocide, fungicide, or herbicide when used as directed or in accordance with commonly recognized practice it shall be injurious to living man or other vertebrate animals, or vegetation, except weeds, to which it is applied, or to the person applying such economic poison; or

(h) if in the case of a plant regulator, defoliant, or desiccant when used as directed it shall be injurious to living man or other vertebrate animals, or vegetation to which it is applied, or to the person applying such economic poison: Provided, That physical or physiological effects on plants or parts thereof shall not be deemed to be injury, when this is the purpose for which the plant regulator, defoliant, or desiccant was applied, in accordance with the label claims and recommendations.

PROHIBITED ACTS

Sec. 3.a. It shall be unlawful for any person to distribute, sell, or offer for sale in any Territory or in the District of Columbia, or to ship or deliver for shipment from any State, Territory, or the District of Columbia to any other State, Territory, or the District of Columbia, or to any foreign country, or to receive in any State, Territory, or the District of Columbia from any other State, Territory, or the District of Columbia, or foreign country, and having so received, deliver or offer to deliver in the original unbroken package to any other person, any of the following:

(1) Any economic poison which is not registered pursuant to the provisions of section 4 of this Act, or any economic poison if any of the claims made for it or any of the directions for its use differ in substance from the representations made in connection with its registration, or if the composition of an economic poison differs from its composition as represented in connection with its registration: Provided, That in the discretion of the Secretary, a change in the labeling or formula of an economic poison may be made within a registration period without requiring reregistration of the product.

(2) Any economic poison unless it is in the registrant's or the manufacturer's unbroken immediate container, and there is affixed to such container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing--

(a) the name and address of the manufacturer, registrant, or person for whom manufactured;
(b) the name, brand, or trade-mark under which said article is sold;
(c) the net weight or measure of the content: Provided, That the Secretary may permit reasonable variations; and
(d) when required by regulation of the Secretary to effectuate the purposes of this Act, the registration number assigned to the article under this Act.

(3) Any economic poison which contains any substance or substances in quantities highly toxic to man, determined as provided in section 6 of this Act, unless the label shall bear, in addition to any other matter required by this Act--

(a) the skull and crossbones;
(b) the word "poison" prominently (IN RED) on a background of distinctly contrasting color; and
(c) a statement of an antidote for the economic poison.

(4) The economic poisons commonly known as standard lead arsenate, basic lead arsenate, calcium arsenate, magnesium arsenate, zinc arsenate, zinc arsenite, sodium fluoride, sodium fluosilicate, and barium fluosilicate unless they have been distinctly colored or discolored as provided by regulations issued in accordance with this Act, or any other white powder economic poison which the Secretary, after investigation of and after public hearing on the necessity for such action for the protection of the public health and the feasibility of such coloration or

discoloration, shall, by regulation, require to be distinctly colored or discolored, unless it has been so colored or discolored: Provided, That the Secretary may exempt any economic poison to the extent that it is intended for a particular use or uses from the coloring or discoloring required or authorized by this section if he determines that such coloring or discoloring for such use or uses is not necessary for the protection of the public health.

(5) Any economic poison which is adulterated or misbranded or any device which is misbranded.

b. Notwithstanding any other provision of this Act, no article shall be deemed in violation of this Act when intended solely for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser.

c. It shall be unlawful--

(1) for any person to detach, alter, deface, or destroy, in whole or in part, any label or labeling provided for in this Act or the rules and regulations promulgated hereunder, or to add any substance to, or take any substance from, an economic poison in a manner that may defeat the purpose of this Act;

(2) for any manufacturer, distributor, dealer, carrier, or other person to refuse, upon a request in writing specifying the nature or kind of economic poison or device to which such request relates, to furnish to or permit any person designated by the Secretary to have access to and to copy such records as authorized by section 5 of this Act;

(3) for any person to give a guaranty or undertaking provided for in section 7 which is false in any particular, except that a person who receives and relies upon a guaranty authorized under section 7 may give a guaranty to the same effect, which guaranty shall contain in addition to his own name and address the name and address of the person residing in the United States from whom he received the guaranty or undertaking; and

(4) for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of section 4 of this Act.

REGISTRATION

Sec. 4.a. Every economic poison which is distributed, sold, or offered for sale in any Territory or the District of Columbia, or which is shipped or delivered for shipment from any State, Territory, or the District of Columbia to any other State, Territory, or the District of Columbia, or which is received from any foreign country shall be registered with the Secretary: Provided, That products which have the same formula, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same economic poison may be registered as a single economic poison; and additional names and labels shall be added by supplement statements; the applicant for registration shall file with the Secretary a statement including--

(1) the name and address of the registrant and the name and address of the person whose name will appear on the label, if other than the registrant;
(2) the name of the economic poison;
(3) a complete copy of the labeling accompanying the economic poison and a statement of all claims to be made for it, including the directions for use; and
(4) if requested by the Secretary, a full description of the tests made and the results thereof upon which the claims are based

b. The Secretary, whenever he deems it necessary for the effective administration of this Act, may require the submission of the complete formula of the economic poison. If it appears to the Secretary that the composition of the article is such as to warrant the proposed claims for it and if the article and its labeling and other material required to be submitted comply with the requirements of section 3 of this Act, he shall register it.

c. If it does not appear to the Secretary that the article is such as to warrant the proposed claims for it or if the article and its labeling and other material required to be submitted do not comply with the provisions of this Act, he shall notify the applicant for registration of the manner in which the article, labeling or other material required to be submitted fail to comply with the Act so as to afford the applicant for registration an opportunity to make the corrections necessary. If, upon receipt of such notice, the applicant for registration does not make the corrections, the Secretary shall refuse to register the article. The Secretary, in accordance with the procedures specified herein, may suspend or cancel the registration of an economic poison whenever it does not appear that the article or its labeling or other material required to be submitted complies with the provisions of this Act. Whenever, the Secretary refuses registration of an economic poison or determines that registration of an economic poison should be cancelled, he shall notify the applicant for registration or the registrant of his action and the reasons therefor. Whenever an application for registration is refused, the applicant, within thirty days after service of notice of such refusal, may file a petition requesting that the matter be referred to an advisory committee or file objections and request a public hearing in accordance with this section. A cancellation of registration shall be effective thirty days after service of the foregoing notice unless within such time the registrant (1) makes the necessary corrections; (2) files a petition requesting that the matter be referred to an advisory committee; or (3)

files objections and requests a public hearing. Each advisory committee shall be composed of experts, qualified in the subject matter and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence, all of which costs may be assessed against the petitioner, unless the committee shall recommend in favor of the petitioner or unless the matter was referred to the advisory committee by the Secretary. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedures to be followed by the committee. The Secretary shall forthwith submit to such committee the application for registration of the article and all relevant data before him. The petitioner, as well as representatives of the United States Department of Agriculture, shall have the right to consult with the advisory committee. As soon as practicable after any such submission, but not later than sixty days thereafter, unless extended by the Secretary for an additional sixty days, the committee shall, after independent study of the data submitted by the Secretary and all other pertinent information available to it, submit a report and recommendation to the Secretary as to the registration of the article, together with all underlying data and a statement of the reasons or basis for the recommendations. After due consideration of the views of the committee and all other data before him, the Secretary shall, within ninety days after receipt of the report and recommendations of the advisory committee, make his determination and issue an order, with findings of fact, with respect

to registration of the article and notify the applicant for registration or registrant. The applicant for registration, or registrant, may, within sixty days from the date of the order of the Secretary, file objections thereto and request a public hearing thereon. In the event a hearing is requested, the Secretary shall, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C. 1006(c)). The National Academy of Sciences shall designate a member of the advisory committee to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing: Provided, That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, but not later than ninety days, the Secretary shall evaluate the data and reports before him, act upon such objections and issue an order granting, denying, or cancelling the registration or requiring modification of the claims or the labeling. Such order shall be based only on substantial evidence of record of such hearing, including any report, recommendations, underlying data, and reason certified to the Secretary by an advisory committee, and shall set forth detailed findings of fact upon which the order is based. In connection with consideration of any registration or application for registration under this section, the Secretary may consult with any other Federal agency or with an advisory committee appointed as herein provided. Notwithstanding the provisions of section 3.c. (4), information relative to formulas of products acquired by authority of this section may be revealed, when necessary under this section, to an advisory committee, or to any Federal agency consulted, or at a public hearing, or in findings of fact issued by the Secretary. All data submitted to an advisory committee

in support of a petition under this section shall be considered confidential by such advisory committee: Provided, That this provision shall not be construed as prohibiting the use of such data by the committee in connection with its consultation with the petitioner or representatives of the United States Department of Agriculture, as provided for herein, and in connection with its report and recommendations to the Secretary. Notwithstanding any other provision of this section, the Secretary may, when he finds that such action is necessary to prevent an imminent hazard to the public, by order, suspend the registration of an economic poison immediately. In such case, he shall give the registrant prompt notice of such action and afford the registrant the opportunity to have the matter submitted to an advisory committee and for an expedited hearing under this section. Final orders of the Secretary under this section shall be subject to judicial review, in accordance with the provisions of subsection d. In no event shall registration of an article be construed as a defense for the commission of any offense prohibited under section 3 of this Act.

d. In a case of actual controversy as to the validity of any order under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when

considered on the record as a whole, including any report and recommendation of an advisory committee. If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order. The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 18 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

e. Notwithstanding any other provision of this Act, registration is not required in the case of an economic poison shipped from one plant to another plant operated by the same person and used solely at such plant as a constituent part to make an economic poison which is registered under this Act.

f. The Secretary is authorized to cancel the registration of any economic poison at the end of a period of five years following the registration of such economic poison or at the end of any five-year period thereafter, unless the registrant, prior to the expiration of each such five-year period, requests in accordance with regulations issued by the Secretary that such registration be continued in effect.

BOOKS AND RECORDS

Sec. 5. For the purposes of enforcing the provisions

of this Act, any manufacturer, distributor, carrier, dealer, or any other person who sells or offers for sale, delivers, or offers for delivery, or who receives or holds any economic poison or device subject to this Act, shall, upon request of any employee of the United States Department of Agriculture or any employee of any State, Territory, or political subdivision, duly designated by the Secretary, furnish or permit such person at all reasonable times to have access to, and to copy all records showing the delivery, movement, or holding of such economic poison or device, including the quantity, the date of shipment and receipt, and the name of the consignor and consignee; and in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the economic poison or device. Notwithstanding this provision, however, the specific evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained.

ENFORCEMENT

Sec. 6.a. The Secretary (except as otherwise provided in this section) is authorized to make rules and regulations for carrying out the provisions of this Act, including the collection and examination of samples of economic poisons and devices subject to this Act and the determination and establishment of suitable names to be used in the ingredient statement. The Secretary is in addition, authorized after opportunity for hearing--

(1) to declare a pest any form of plant or animal life or virus which is injurious to plants, man, domestic animals, articles, or substances;
(2) to determine economic poisons, and quantities of substances contained in economic poisons, which are highly toxic to man; and
(3) to determine standards of coloring or discoloring for economic poisons, and to subject economic poisons to the requirements of section 3.a.(4) of this Act.

b. The Secretary of the Treasury and the Secretary of Agriculture shall jointly prescribe the regulations for the enforcement of section 10 of this Act.

c. The examination of economic poisons or devices shall be made in the United States Department of Agriculture or elsewhere as the Secretary may designate for the purpose of determining from such examination whether they comply with the requirements of this Act, and if it shall appear from any such examination that they fail to comply with the requirements of this Act, the Secretary shall cause notice to be given to the person against whom criminal proceedings are contemplated. Any person so notified shall be given an opportunity to present his views, either orally or in writing, with regard to such contemplated proceedings, and if in the opinion of the Secretary it appears that the provisions of this Act have been violated by such person, then the Secretary shall certify the facts to the proper United States attorney, with a copy of the results of the analysis or the examination of such article: Provided, That nothing in this Act shall be construed as requiring the Secretary to report for prosecution or for the institution of libel proceedings minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice of warning.

d. It shall be the duty of each United States attorney, to whom the Secretary or his agents shall report any violation of this Act, to cause appropriate proceedings to be commenced and prosecuted in the proper courts of the United States without delay.

e. The Secretary shall, by publication in such manner as he may prescribe, give notice of all judgments entered in actions instituted under the authority of this Act.

EXEMPTIONS

Sec. 7.a. The penalties provided for a violation of section 3.a. of this Act shall not apply to--

(1) any person who establishes a guaranty signed by, and containing the name and address of, the registrant or person residing in the United States from whom he purchased and received in good faith the article in the same unbroken package, to the effect that the article was lawfully registered at the time of sale and delivery to him, and that it complies with the other requirements of this Act, designating this Act. In such case the guarantor shall be subject to the penalties which would otherwise attach to the person holding the guaranty under the provision of this Act;

(2) any carrier while lawfully engaged in transporting an economic poison or device if such carrier upon request by a person duly designated by the Secretary shall permit such person to copy all records showing the transactions in and movement of the articles;

(3) to public officials while engaged in the performance of their official duties;

(4) to the manufacturer or shipper of an economic poison for experimental use only by or under the supervision of any Federal or State agency authorized by law to conduct research in the field of economic poisons; or by others if a permit has been obtained before shipment in accordance with regulations promulgated by the Secretary.

PENALTIES

Sec. 8.a. Any person violating section 3.a.(1) of this Act shall be guilty of a misdemeanor and shall on conviction be fined not more than $1,000.

b. Any person violating any provision other than section 3.a.(1) of this Act shall be guilty of a misdemeanor and shall upon conviction be fined not more than $500 for the first offense, and on conviction for each subsequent offense be fined not more than $1,000 or imprisoned for not more than one year, or both such fine and imprisonment: Provided, That an offense committed more than five years after the last previous conviction shall be considered a first offense. An article the registration of which has been terminated may not again be registered unless the article, its labeling, and other material required to be submitted

appear to the Secretary to comply with all the requirements of this Act.

c. Notwithstanding any other provision of this Section, in case any person, with intent to defraud, uses or reveals information relative to formulas of products acquired under the authority of section 4 of this Act, he shall be fined not more than $10,000 or imprisoned for not more than three years, or both such fine and imprisonment.

d. When construing and enforcing the provisions of this Act, the act, omission, or failure, of any officer, agent, or other person acting for or employed by any person shall in every case be also deemed to be the act, omission, or failure of such person as well as that of the person employed.

SEIZURES

Sec. 9.a. Any economic poison or device that is being transported from one State, Territory, or District to another, or, having been transported, remains unsold or in original unbroken packages, or that is sold or offered for sale in the District of Columbia or any Territory, or that is imported from a foreign country, shall be liable to be proceeded against in any district court of the United States in the district where it is found and seized for confiscation by a process of libel for condemnation--

(1) in the case of an economic poison--

(a) if it is adulterated or misbranded;
(b) if it is not registered pursuant to the provisions of section 4 of this Act;
(c) if it fails to bear on its label the information required by this Act;
(d) if it is a white powder, economic poison, and is not colored as required under this Act; or

(2) in the case of a device if it is misbranded.

b. If the article is condemned it shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the legal costs, shall be paid into the Treasury of the United States, but the article shall not be sold contrary to the provisions of this Act or of the laws of the jurisdiction in which it is sold; Provided, That upon the payments of the costs of the libel proceedings and the execution and delivery of a good and sufficient bond conditioned that the article shall not be sold or otherwise disposed of contrary to the provisions of this Act or the laws of any State, Territory, or District in which sold, the court may direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

c. When a decree of condemnation is entered against the article, court costs and fees, storage, and other proper expenses shall be awarded against the person, if any, intervening as claimant of the article.

IMPORTS

Sec. 10. The Secretary of the Treasury shall notify the Secretary of Agriculture of the arrival of economic poisons and devices offered for importation and shall deliver to the Secretary of Agriculture, upon his request, samples of economic poisons or devices which are being imported or offered for import into the United States, giving notice to the owner or consignee, who may appear before the Secretary of Agriculture and have the right to introduce testimony. If it appears from the examination of a sample that it is adulterated, or misbranded or otherwise violates the prohibitions set forth in this Act, or is otherwise dangerous to the health of the people of the United States, or is of a kind forbidden entry into or forbidden to be sold or restricted in sale in the country in which it is made or from which it is exported, the said article may be refused admission, and the Secretary of the Treasury

shall refuse delivery to the consignee and shall cause the destruction of any goods refused delivery which shall not be exported by the consignee within three months from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe: Provided, That the Secretary of the Treasury may deliver to the consignee such goods pending examination and decision in the matter on execution of penal bond for the amount of the full invoice value of such goods, together with the duty thereon, and on refusal to return such goods for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of said bond: And provided further, That all charges for storage, cartage, and labor on goods which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

DELEGATION OF DUTIES

Sec. 11. All authority vested in the Secretary by virtue of the provisions of this Act may with like force and effect be executed by such employees of the United States Department of Agriculture as the Secretary may designate for the purpose.

AUTHORIZATION FOR APPROPRIATIONS AND EXPENDITURES

Sec. 12.a. There is hereby authorized to be appropriated, out of any moneys in the Treasury not otherwise appropriated, such sums as may be necessary for the purposes and administration of this Act. In order to carry out the provisions of this Act, which take effect prior to the repeal of the Insecticide Act of 1910, appropriations available for the enforcement of such Act are authorized to be made available.

b. The Secretary is authorized from the funds appropriated for this Act to make such expenditures as he deems necessary, including rents, travel supplies, books, samples, testing devices, furniture, equipment, and such other expenses as may be necessary to the administration of this Act.

COOPERATION

Sec. 13. The Secretary is authorized to cooperate with any other department or agency of the Federal Government and with the official agricultural or other regulatory agency of any State, or any State, Territory, District, possession, or any political subdivision thereof, in carrying out the provisions of this Act, and in securing uniformity of regulations.

SEPARABILITY

Sec. 14. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of this Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

Appendix 4.—Supplemental Information Relating to Administration of Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Department of Agriculture, Agricultural Research Service

SUPPLEMENTAL INFORMATION RELATING TO ADMINISTRATION OF FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Functions of Pesticides Regulation Division

The Federal Insecticide, Fungicide, and Rodenticide Act, which was enacted by Congress in 1947, requires that all economic poisons must be registered with the Department of Agriculture prior to shipment in interstate commerce. The act has since been amended to eliminate registration under protest, to require the registration number to appear on the label, and to bring such materials as plant regulators, desiccants, and and defoliants under the requirements of the act. The act regulates shipment in interstate commerce and not the intrastate movement or the use of pesticides.

The Pesticides Regulation Division of the Agricultural Research Service is directly responsible for the registration and enforcement of the act. Before a product can be registered, the manufacturer or formulator must file a formal application, submit five copies of the proposed labeling, a statement of complete chemical composition of the product, and extensive data on both efficacy and safety.

The new chemicals evaluation staff first reviews the label for accuracy of chemical composition, ingredient statement, net contents, chemical nomenclature, and product name.

The product evaluation staff, made up of specialists in entomology, plant pathology, agronomy, bacteriology, and animal biology, reviews the labels and data for effectiveness. Among the criteria used are the pests to be controlled, dosage and rate of application, soil persistence, metabolism, phytotoxicity, migration, translocation, and method of application.

The pesticides safety evaluation staff reviews the toxicological data with respect to safety to man, fish, and wildlife, and other beneficial animals. The principal criteria used in the safety evaluation are the results of acute, oral, dermal, and inhalation studies, subacute feeding studies, eye and skin irritation, sensitization, neurotoxicity, reproduction, and carcinogenic studies. On the basis of the data, it can be determined whether the front panel of the label shall carry the signal word "Danger," "Warning," or "Caution," and what precautionary statements are necessary, which, if complied with, are adequate to prevent injury to living man and other vertebrate animals, vegetation, and useful invertebrate animals.

If the product is to be used on food or feed, careful consideration is given to residues that are likely to occur from such use and in which case the matter is referred to the Food and Drug Administration for establishing a tolerance.

After the scientific review has been completed, the application is again reviewed in its entirety to determine if the product is acceptable for registration. If data are inadequate, the applicant is so advised and registration is withheld until all requirements have been satisfied. If it appears that registration is in order, the label and data are referred to the Department of the Interior and/or the Department of Health, Education, and Welfare as provided for under the interdepartmental agreement. The purpose of this agreement is to give the other Departments an opportunity to advise the Department of Agriculture of any changes in labeling that might be necessary to further protect the public, or to protect fish and wildlife. Our scientists are in day-to-day communication with HEW and Interior.

When all requirements have been satisfied, the product is registered and the applicant is assigned a registration number. When the product is shipped in interstate commerce it is under constant surveillance to determine if it is in com-

pliance with the law. The Pesticides Regulation Division maintains a field inspection force located in various regions of the United States, who sample economic poisons wherever they are found, and send them to the laboratories for investigation. If a product is found to be in violation of the act, the manufacturer or shipper is subject to criminal prosecution. The product may be seized or, if it poses a serious threat to health, the manufacturer is requested to withdraw it from the market. In fiscal year 1969, we sampled more than 8,000 products shipped in interstate commerce.

The Pesticides Regulation Division maintains close liaison with State officials through the Association of American Pesticide Control Officials in developing uniform registration requirements and enforcement procedures.

What Products Are Registered?

More than 45,000 products made from one or more of 900 chemical compounds are currently registered by USDA. Of these, farmers use pesticides to fight harmful weeds, insects, plant diseases, and other pests attacking their livestock and feed crops; plant regulators to produce seedless fruits and vegetables and to prevent premature dropping of fruit; and plant defoliants and desiccants to cause leaves to drop or plants to mature uniformly so that mechanical harvesting can be used more efficiently.

Although farmers use by far the largest volume of the pesticides produced in this country, approximately half of the pesticide products registered by USDA are designed for nonfarm uses around or in homes, apartment buildings, and industrial plants.

Industrial uses of chemical products registered as pesticides are quite varied. For example, manufacturers use chemical pesticides against fungi in literally thousands of products ranging from asphalt, paint, and plastics to jet fuel. Other pesticides are used by industry to make such products longer lasting and more attractive to consumers.

All sterilizing, disinfecting, sanitizing, germicidal, and bacteria killing chemicals—except those sold exclusively for use on or in the living body of man or other animals—are classified as "pesticides" and must be registered with USDA. These include products to sterilize and disinfect surgical and dental instruments, barber shop and beauty parlor instruments and equipment, dairy equipment, and such restaurant equipment as dishes and glasses.

Homeowners and apartment dwellers alike use pesticides practically every day. The housewife fights such insects as roaches and ants with pesticides; she combats mildew and other fungi in clothing with fungicides; and she applies detergent sanitizers in her laundry and antibacterial sprays in her bathrooms and kitchens to keep them sanitary and clean smelling.

Homeowners regularly use insecticides on their lawns, rose bushes, and other ornamentals to protect them against insects. They also apply fungicides on lawns to control grass diseases and herbicides on lawns, driveways, and other areas to control weeds. All of these types of chemicals are registered by USDA.

What Are the Requirements?

USDA scientists give primary consideration to the safety of users and consumers when setting the rigid standards that pesticide products must meet before they are accepted for registration.

Once an application for registration is submitted to the Pesticides Regulation Division, the scientific staff begins an exhaustive review of supporting evidence provided by the manufacturer. Pertinent information available from other sources is also considered.

The Division's pharmacology and toxicology staff review proposed uses of pesticide formulations to determine whether or not such uses would be hazardous to our health and if such hazards can be avoided. Chemists review the application from the standpoint of the chemical composition and the compatibility of the mixture. They also evaluate the scientific data supporting the manufacturer's claims about the amounts and duration of any resdues resulting from the use of a pesticide.

Entomologists, weed control specialists, bacteriologists, plant pathologists and physiologists, nematologists, and animal biologists study the application from the standpoint of their particular areas of competence. They determine how effective a pesticide would be against the pests listed on the label—and whether or not the product would cause unwanted side effects.

If the review staff decides that the product would be useful and can be used safely when directions are carefully followed, the product may then be registered.

What About Residue Tolerances?

As additional protection, pesticides to be used on food and feed crops must meet special requirements for registration. Such pesticides cannot be registered until the Food and Drug Administration of the Department of Health, Education, and Welfare has determined how much residue—if any—can safely be permitted to remain on food or feed crops. FDA must otherwise determine if a product can be exempted from this requirement. Pesticides must be very low in toxicity, however, to be exempted from tolerance requirements. Pesticides used in a way not involving food or feed do not require a tolerance.

In requesting FDA to establish a permissible residue level, the applicant must submit suitable scientific data on the toxicity of a chemical and the amount of residue likely to result from its use. On the basis of this and other available information, FDA determines how much residue—if any—may be permitted. USDA will not register the product until satisfied that any residue will not exceed the level established by FDA.

Although responsible for the registration of pesticides, USDA officials consult with and seek the advice of experts at other Federal agencies to further insure that the public interest is fully protected. USDA routinely refers pesticide labels to the Public Health Service, for example, for the formal opinions of health authorities. Applications involving proposed outdoor uses of pesticides are referred to the Fish and Wildlife Service of the Department of the Interior for review and comment about the possible adverse effects of the pesticide on fish and wildlife. The opinions of such agencies are considered fully before USDA officials decide on a registration application.

How Are Standards Enforced?

USDA carries out enforcement activities to make sure that pesticide products being marketed interstate continue to meet the standards required for registration and sale. Pesticides Regulation Division inspectors located at strategic points throughout the United States collect samples of pesticides and send them to a USDA laboratory for testing. USDA scientists analyze these samples with highly sensitive equipment to make sure the product contains all the ingredients in the amounts listed on the label and that the product is not adulterated with chemicals or other materials not listed on the label.

USDA scientists also make laboratory and field tests on a regular basis to check the effectiveness of registered pesticide products. And they conduct pharmacological tests to see that safety precautions continue to be adequate.

If a product is found to be misrepresented or faulty in any way, appropriate actions are taken to correct the situation. In a minor violation, an informal notice to the company may be sufficient. More serious violations may result in a formal notice of violation, seizure of the company's goods, or even prosecution of the violator. Registration for a product may be suspended or canceled at any time if necessary to protect the public interest.

Enforcement

1. *Citations*

Section 6.c. of the act (7 U.S.C. 135d(c)) provides that whenever an economic poison or device is found to be in violation of the act, a notice shall be given to the person against whom criminal proceedings are contemplated. This citation procedure is intended to be applicable to all violations of the act. Its primary purpose is to give the person cited an opportunity to submit any facts or explanations relevant to the alleged violation.

First, the citation procedure is a part of the criminal procedures of the act. The citation is the statutory prerequisite to criminal prosecution. Therefore, a citation is something more than a mere perfunctory notice of violation. It is a serious matter, and it must be viewed as a serious matter by both the regulatory agency and the regulated industry.

In determining the action which should be taken following citation, we carefully review the answer to each citation from the standpoint of (1) the nature of the violation, (2) the explanation given by the person cited as to the reason for the alleged violation, and (3) the assurances given concerning the corrective action to be taken.

2. *Criminal prosecution*

It is not required under the act that all violations be referred to the Department of Justice for prosecution. Specifically, the act provides that the Department of Agriculture is not required to send to the Department of Justice violations

of a minor nature where a determination has been made that the public interest will be served by a suitable notice of warning.

The enforcement of the act through criminal prosecution is not only required by the statute, but supports and strengthens the other enforcement activities as well. For example, the citation procedure becomes fully effective only when it relates to a strong prosecution program.

In December 1967, a new prosecution and import section was created in the Pesticides Regulation Division. The purpose in creating this section was not only to establish more effective procedures for the handling of prosecutions, but also to focus attention upon the fact that prosecutions are an important part of the enforcement program.

In any matter where we believe criminal prosecution should be initiated, a criminal prosecution file is prepared in the prosecution and import section and the matter is referred to the Office of the General Counsel (OGC) of the Department with a recommendation that prosecution be initiated.

Our present operating guidelines for the referral of cases to OGC are that we will recommend prosecution in all cases where (1) the evidence indicates that the violation was willful, (2) violation is of a serious nature (for example, significant deficiency of active ingredient or contamination) and is the result of apparent gross negligence, or (3) the company has engaged in repeated violations.

3. *Recall of Products*

The FIFRA contains no provisions relating to the recall of products. However, cooperative action by manufacturers in recalling defective or hazardous products is the most effective and efficient means of removing violative products from channels of trade.

In September 1967, the Pesticides Regulation Division made its first request to a manufacturer that a complete recall of a product be initiated. Since that time recalls have become an integral part of our enforcement program. It is our intention to make increased use of recalls in the future. We believe that recalls should be initiated in all cases involving products which are potentially hazardous or ineffective. Recently, our internal procedures were revised to assure that products in the potentially hazardous or ineffective category are "flagged" at the earliest possible time and thereafter handled on an expedited basis.

4. *Seizures*

Recalls by the manufacturer or shipper are the most effective and efficient means of removing violative products from the market. To the extent that recall actions are effective there will be no necessity to resort to seizure actions. Therefore, our seizure activities are primarily directed toward the removal from the market of potentially hazardous or ineffective products where recall action is not effective. This involves (1) obtaining from the manufacturer or shipper information concerning all consignees of the violative product, (2) obtaining samples of such product at every possible product location, and (3) the initiation of seizure actions with respect to such product in every instance where supporting data is obtained.

5. *Section 4.c.—Cancellation of Registration*

Section 4.c. of the act (7 U.S.C. 135b(c)) authorizes the Secretary to cancel the registration of a product whenever it does not appear that the product or its labeling comply with the provisions of the act. The statutory procedure for the cancellation of registration in this situation is to notify the registrant of the determination that registration of the product should be canceled, together with the reasons for such determination, and to afford the registrant a period of 30 days within which to make any necessary corrections. In addition to the opportunity to make corrections, the registrant may file a petition requesting that the matter be referred to an advisory committee or file objections and request a public hearing.

6. *Correspondence*

Violations which are considered minor in nature are handled under the correspondence procedure. In these cases, the Pesticide Regulation Division notifies the manufacturer or shipper of its findings in order that the persons so notified may take such action as is warranted. The emphasis here is on corrective action prior to a full-blown violation.

Whenever the evidence obtained through our sampling and testing program reveals that a product is inherently defective, the proper and most efficient action is a section 4.c. notice of cancellation action. Procedures have been established for the use of such an action in our overall enforcement program.

Appendix 5.—Information Concerning Recall Actions Initiated by the Pesticides Regulation Division During the Period July 1, 1968–April 30, 1969

Information Concerning Recall Actions, July 1, 1968–April 30, 1969

The information set forth in the attached tabulation relates to 23 Pesticides Regulation Division initiated recalls during the period July 1, 1968–April 30, 1969, in which the information received is substantially complete.

In each of these cases it was concluded that the amount of product withdrawn represented the entire quantity of the product known to be on the market. In these cases the companies were requested to make a complete record check in order to identify all consignees of the product, or product locations, and to have the product returned. The companies were also requested to inform Pesticides Regulation Division of (*a*) the steps taken to recall the product, and (*b*) the completeness of the recall action. In some, but not all, of these cases, inspectors of Pesticides Regulation Division assisted the companies in the recall procedures and verified the reports of the recall actions.

Procedures have been established to assure that all product locations are covered in any recall action and that an accurate appraisal can be made of the completeness of the recall action.

U.S. DEPARTMENT OF AGRICULTURE—AGRICULTURAL RESEARCH SERVICE

PRD INITIATED RECALLS, JULY 1, 1968–APR. 30, 1969

Recall number	Product name	Manufacturer (shipper)	Nature of violation and/or danger	Number of product locations contacted	Amount of product withdrawn
82660	Patterson's Cyanobrik	Patterson Chemical Co., Inc., Kansas City, Mo.	Potential hazard; sodium cyanide brickettes; not registered; no warning or caution labeling.	9	7, 5-pound drums.
66125	Gordon's Grub Dust	Gordon Chemical Co., Inc., Kansas City, Kans.	Potential hazard; contaminated with DDT and dieldrin; ineffective; deficient in rotenone.	6	223 pounds.
62120	Stephenson 10% Sevin Dust	Stephenson Chemical Co., Inc., College Park, Ga.	Potential hazard; contaminated with DDT and chlordane.	1	1,450 pounds.
62123	Stephenson 1% Rotenone Dust	Stephenson Chemical Co., Inc., College Park, Ga.	do	16	20, 1-pound cans.
62090	Unico Lindane Wettable Powder	United Co-Operatives, Inc., Alliance, Ohio	Potential hazard; contaminated with DDT, dieldrin, and chlordane.	7	534 pounds.
65228	Parathion 4 lbs.	Olin Mathieson Chemical Corp., Little Rock, Ark.	Potential hazard; contaminated with aldrin	1	95 gallons.
57082 62047 60700	Nutro Tomato Vegetable Dust	The Borden Chemical Co., Smith-Douglass Division, Norfolk, Va.	Ineffective; deficient in active ingredient zineb	187	60 pounds.
62165	Watkins Fly Bait	Watkins Products, Inc., Winona, Minn.	Ineffective; deficient in active ingredient DDVP	826	17,764 pounds.
63252	Nico-Fume Pressure Fumigator	Black Leaf Products Co., Chicago, Ill.	Potential hazard; product did not bear adequate warning or caution statements.	3	480 pounds.
60788	Germelene Triple-Action Cleaner Concentrate.	The Davies-Young Soap Co., Dayton, Ohio	Ineffective disinfectant; misbranded	42	220 gallons; 4,600 pieces of literature.
78751	Carbola Super D Dry Dust	Carbola Chemical Co., Inc., Natural Bridge, N.Y.	Ineffective; deficient in active ingredient malathion	10	2,280 pounds.
65641	Endrin 1.6 Lb. Emulsifiable	Olin Mathieson Chemical Corp., Little Rock, Ark.	Potential hazard; contaminated with methyl parathion.	3	250 gallons.

60381	Spray Pak Dubl Duty Germicidal and Deodorizer, et al.	Chase Products Co., Broadview, Ill.	Potential hazard; ineffective disinfectant	84	6,410 cases (76,920 units).
82875	Niagara Polyram 5 DDT 5 Dust	FMC Corp., Niagara Chemical Division Middleport, N.Y.	Ineffective; deficient in DDT	23	1,000 pounds.
61470	Winans Pine Disinfectant	Brite Products Co., Inc. Philadelphia, Pa	Deficient in active ingredient; improper labeling	2	5 gallons.
62471	Parathion 2 Lb	Baird & McGuire, Inc., Holbrook, Mass.	Potential hazard; parathion shipped in unlabeled containers.	3	34 1-gallon cans.
63364	Gurney's 10% Aldrin Granules	Economy Products Co., Inc. Shenandoah, Iowa	Potential hazard; label bore directions for use which would produce illegal aldrin residues.	1	475 pounds.
63942	Niagara Miscible	FMC Corp., Niagara Chemical Division, Middleport, N.Y.	Potential hazard; label bore directions for use which would produce illegal endrin residues; product not registered.	3	462 gallons.
76656	Blue Grotto Disinfectant	Hysan Products Co., Chicago, Ill.	Ineffective disinfectant	53	1,280 gallons; 791 gallons on hand at manufacturers.
62759	Alko-Septol	Analab Laboratories, Inc., Somerville, Mass.	do	7	23 gallons and 6 pints.
61679	The Mal-Marc Dry Sterilizer	Mal-Marc Corp., Arverne, Long Island, N.Y.	do	47	Not available.
63325	Star Chemicals Bug Strip	Star Chemicals, Belleville, Mich.	Potential hazard; unregistered DDVP insecticide strip.	5	4,038 strips.
66514					
65656	YM E1.6–1.6E Methyl Parathion and Endrin	Swift & Co., Agrichem Division, Memphis, Tenn.	Potential hazard; contaminated with DDT	2	125 gallons; 865 gallons in manufacturing warehouse.

APPENDIX 6.—REPORT OF THE TASK FORCE ON THE PESTICIDES REGULATION DIVISION, NOVEMBER 1965

NATIONAL ACADEMY OF SCIENCES
NATIONAL RESEARCH COUNCIL

DIVISION OF CHEMISTRY AND CHEMICAL TECHNOLOGY
2101 Constitution Ave., Washington, D. C. 20418

ADVISORY CENTER ON TOXICOLOGY — HARRY W. HAYS, *Director*

November 19, 1965

Dr. Robert J. Anderson
Deputy Director
Agricultural Research Service
U. S. Department of Agriculture
Washington, D. C. 20250

Dear Dr. Anderson:

On behalf of the Task Force assigned to review the registration and enforcement procedures of the Pesticides Regulation Division of the Department of Agriculture, I am pleased to submit the enclosed report.

Throughout this study, we have been mindful of the fact that our primary mission was to suggest ways and means of correcting any deficiencies that were found to exist and not to fix the blame. Considering the magnitude of the Division's responsibilities in providing for the safety and effectiveness of the thousands of formulations registered with the Department of Agriculture, the advances in research and technology, and the pressures of industry to market its products, we believe the Division has, over the past twenty years, done a very creditable job. However, circumstances surrounding the widespread use of pesticides require a modern and efficient organization to meet its responsibilities.

The organizational chart attached to this report is meant to be illustrative of how we believe the Division should be organized. The precise titles will, of necessity, be dictated by policy within the Department of Agriculture.

While this report is not considered to be confidential, it does deal with sensitive areas and some of the statements made could be distorted or misinterpreted. Many of the conclusions were based upon impressions gained from personal interviews and we would not wish to compromise the confidence of those who gave us assistance. We hope, therefore, that the distribution of the report will be limited to those who have a need to know.

It has been a pleasure and a privilege to serve as Chairman of the Task Force. We have tried to make an objective and thorough study of the problems and I sincerely appreciate the efforts of each of the participants.

Sincerely yours,

Harry W. Hays

HWH:mst

Harry W. Hays, Ph. D., Chairman
Task Force on the Pesticides
Regulation Division

Enclosure

REPORT OF THE TASK FORCE

ON THE

PESTICIDES REGULATION DIVISION

November 1965

PESTICIDES REGULATION TASK FORCE

HARRY W. HAYS, Chairman, Director, Advisory Center on Toxicology, National Academy of Sciences-National Research Council, Washington, D. C.

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REPORT OF TASK FORCE ON PESTICIDES REGULATION DIVISION

I. Purpose of Study

The Federal Insecticide, Fungicide and Rodenticide Act of 1947 provides for the regulation of the marketing of economic poisons and devices in interstate commerce. During the past decade there has been a steady increase in the discovery and development of new pesticide chemicals and as of January 1965, over sixty thousand formulations have been registered with the U. S. Department of Agriculture. The greatly expanded registration and enforcement program of the Pesticides Regulation Division has made it necessary to study ways and means of meeting this increased work load and for this reason, the Secretary of Agriculture, Orville L. Freeman, appointed a Task Force to:

a. Review and evaluate the mechanics of registration, enforcement, management, and organization of the Pesticides Regulation Division in administering the Federal Insecticide, Fungicide, and Rodenticide Act, and to make recommendations for their improvement.

b. Review and evaluate the criteria used in determining the safety and efficacy of pesticides and other agricultural chemicals.

c. Review and evaluate work performance efficiency in processing registration applications and recommend changes, including automation, which might be used to improve that efficiency.

d. Review and evaluate the environment for scientists as it relates to initiative and attraction of competent personnel.

e. Explore the adequacies of space, facilities, and financial support of the Division's program.

f. Review the Interagency Agreement as it relates to the registration of pesticides.

g. Explore ways to improve cooperation between the Pesticides Regulation Division and industry which would be mutually beneficial.

h. Review the procedures for cooperation and liaison with units within the Department of Agriculture and with other Federal and State agencies.

In an effort to make a thorough study and critical review of the problems assigned to the Task Force, the Chairman invited representatives of the Agricultural Research Service including the Division's staff, representatives of the Department of Health, Education and Welfare and the Department of the Interior, and representatives of industry to appear before the group to discuss problems relating to the registration of pesticides. The Task Force wishes to express its sincere appreciation to all those who have contributed so generously to this study.

II. Comments on Regulations

The first major change in the Federal Insecticide Act of 1910 was made in 1947 with the passage of the Federal Insecticide, Fungicide and Rodenticide Act (61 Stat. 163). Since then, several amendments have been added, which, among other things, extended the scope of the Act to include nematocides, plant growth regulators, defoliants and desiccants.

The Act provides that all economic poisons must be registered

with the U. S. Department of Agriculture before being shipped in interstate commerce. The Regulations for registration and enforcement of the Act are administered by the Pesticides Regulation Division of the Agricultural Research Service of the U. S. Department of Agriculture. The prime objective in administering the Act and Regulations is the protection of the public. A pesticide chemical must not only be effective against a particular pest or pests, but also suitable of being used with safety to humans, crops, livestock, and wildlife. To this end, the Act and Regulations require that all applications must be supported by convincing evidence of safety and effectiveness before registration is granted and that the product must be properly labelled.

III. Organization and Management

A. Relation of Pesticides Regulation Division to Agricultural Research Service

The history of pesticide regulations dates back to 1910 when it was known as the Insecticide, Fungicide Board. From 1930-1954 it was housed in the Agricultural Marketing Service with the exception of two years when it was a part of the War Food Administration. Since then it has been a part of the Agricultural Research Service under

the general supervision of the Deputy Administrator for Regulatory Programs. This relationship of the Pesticides Regulation Division to the Agricultural Research Service affords the opportunity for close cooperation between the activities of the two groups in evaluating the safety and effectiveness of pesticides and it therefore seems reasonable that the regulatory division should be closely allied to the research organization.

In reviewing the registration procedures, the Task Force gained the impression that products have been registered on the basis of professional judgment in lieu of adequate data with no record being made of the basis for action. Information is often available in the Agricultural Research Service to guide registration of insecticides, fungicides, herbicides, and nematocides and the Division should be encouraged to work closely with the research laboratories of the Agricultural Research Service. There is, however, insufficient research effort in the Agricultural Research Service to guide registration and enforcement in areas of animal biology, bacteriology, and pharmacology.

B. Organization of Pesticides Regulation Division

At the present time the Pesticides Regulation Division is composed of a Director's office and a Registration and Enforcement Branch which includes registration and enforcement sections. In addition, there is a Technical Evaluation Staff with six scientific sections: Animal Biology, Bacteriology, Entomology, Plant Biology, Chemistry, and Pharmacology. The Branch Chief and each of the Section Heads report directly to the Director of the Division.

The responsibilities of the Pesticides Regulation Division require a decisive and forceful administration and steps should be taken to develop, at all levels, leadership, initiative, and a sense of urgency in accomplishing the job at hand.

C. Registration

Essentially, three different categories of applications are received by the Pesticides Regulation Division: (1) a new pesticidal chemical; (2) new uses for a pesticide already registered, and (3) new registrations for old products but by different distributors, formulators, or manufacturers. Currently, applications for registration of pesticides in all categories are given the same review process.

The 1964 amendment of the Regulations required that the labels of all registered products must bear a registration number and certain additional precautionary statements. Since neither industry nor the Division was prepared to meet the effective dates, extensions have been granted to 1966. During the past fiscal year, several hundred applications were received from companies which had not previously registered any products with the Department of Agriculture. It was also noted that the Division has had to request additional information on more than fifty per cent of all the applications received. These, as well as other problems associated with registration, have resulted in a substantial increase in the work load of the Division.

1. Work Flow

All applications and approved registrations are kept in uniform jackets and when applications are received in the Registration Section, a check is made of the manufacturer's jacket(s). If there is none, jackets are prepared and the applications given a manufacturer's number. The jackets are then delivered by messenger to the Chemistry Section where they are reviewed for statement of composition, ingredient statement on the label, brand name, methods of analysis, and necessary warnings

as to fire hazard. If the application does not contain a statement of complete composition, a letter is sent to the applicant requesting such information and the jacket(s) held in the Chemistry Section until a statement is received. When Chemistry has completed its review, the applications are delivered by messenger to the appropriate section for evaluation and comments. These reviews consist of comparing directions for use with established use patterns for the chemicals listed in the "Summary of Registered Agricultural Pesticide Chemical Uses." If the proposed use does not comply with the established use pattern, the application is not registered and the jacket is held until adequate data are received to support the claims. If the proposed uses involve food or feed, the jacket is marked for "residue review" and returned to the Chemistry Section for further study, including possible referral to the Food and Drug Administration.

After review for efficacy, the applications are forwarded to the Pharmacology Section for evaluation and comments on safety. When completed they are returned to the Registration Section along with the penciled comments of each of the sections. Copies of the proposed labels are forwarded to the U. S. Public Health Service and

the Department of the Interior for review and comments. These are returned within a week and if either agency requests changes in the precautionary labeling, the jackets are again forwarded to the appropriate sections in the Division. The comments of the Public Health Service and Interior are then combined with those of the Division staff and the Registration Section prepares a letter to the applicant approving or withholding registration.

All records are kept in the Registration Section and are coded for future reference. When a new chemical is registered, the jacket is referred to the Director's Office where an administrative letter is prepared for distribution to the State regulatory agencies. The Task Force was advised that the average time for registration is approximately eight weeks.

It is our opinion that the procedures currently used to process the renewal of registered products are not efficient for handling the present work load. We find no justification for each section following the same procedures for reviewing renewals and routine applications. Once the use pattern has been established, it should be a relatively simple matter for one office to process these applications. We

therefore strongly urge the establishment of a Renewal Section under the supervision of a Deputy Director for Registration which would be responsible for the review and approval of all routine applications. This would drastically curtail the flow of applications from one section to another and greatly reduce the time required for processing a previously registered product. The Task Force also recommends the creation of a New Applications Section under the supervision of the Deputy Director for Registration which would be responsible for review and approval of all new and unusual applications.

Before applications are submitted to the Renewal or New Applications Sections, they should be reviewed for completeness of information required by the Regulations. If additional data are needed for either new or renewal applications, the Deputy Director for Registration should make a formal request. This would prevent the registrant from being contacted by several sections acting independently and also reduce the flow of correspondence.

The physical problem of handling the large volume of labels and accompanying data involving registration is so great that it is mandatory that a system be developed to provide an adequate and

orderly flow of material through the Division. There is also an urgent need to develop a filing and storage system to permit ready retrieval of pertinent data. Nowhere is there any control of routing of jackets and it is difficult, if not impossible, to locate a jacket at any given time. Jackets have been lost for varying periods and in some cases it has been necessary for the registrant to file another application.

2. Notice of Renewal of Registration

The Act and Regulations provide that all economic poisons registered with the Department of Agriculture be re-registered every five years. Prior to the end of this period, the companies are notified that registration will be cancelled within 30 days unless the Pesticides Regulation Division is informed of intent to continue the registration. If no reply is received within the 30-day period, a second notice is sent by registered mail informing the registrant that registration will be cancelled unless the Division is notified within the next 30 days.

We feel that the 30-day notice of intent to cancel a registration as provided in the Act is the only notice required and that the practice of sending a second notice should be discontinued. It should be the responsibility of any company registering a product with the

Department of Agriculture to comply with this provision of the law.

3. Procedures for Requesting Information and Replies to Inquiries

It was observed that, in the process of reviewing applications, additional information is being requested independently by various sections in the Division and in some cases by handwritten letters. As previously mentioned, the Chemistry Section frequently asks for information on inert ingredients and holds the jacket until it is received. When the jacket is finally received in the Registration Section, further information may be required and the registrant contacted again. There is no follow-up of any of this correspondence and if the registrant does not reply, the jacket is filed and no further action is taken.

This lack of coordination within the various sections is confusing to industry, delays registration and creates a lack of confidence in the Pesticides Regulation Division. This situation should not be allowed to continue and steps should be taken to avoid duplication of effort by assigning this responsibility to the Deputy Director for Registration. Under no circumstances should handwritten letters be sent to registrants.

There have also been complaints about the method of handling replies to incoming correspondence. The current procedure of preparing letters in draft for review by the Director is a very cumbersome process and should be discontinued. We think routine requests should be answered over the signature of a senior professional staff member, while letters involving Department of Agriculture policy should be prepared in final form and forwarded to the Director's office for signature.

4. Maintenance of Files

At the present time all registration and case development files are maintained in a central location and under the control of the Director's office. The Task Force noted first of all, that there is inadequate space in the file room and there are not nearly enough files to handle all of the jacket material so that documents are being housed in unlocked files and boxes with no security control. In addition, jackets containing confidential information are often left on desk tops and in unlocked drawers. We do not question anyone's integrity but the maintenance of security control is the responsibility of the Pesticides Regulation Division since the information is acquired under

authority of Section 4 of the Act. Industry representatives have expressed concern over the handling of applications, particularly those containing confidential information, and we fully agree that every registrant is entitled to the fullest protection possible. The law provides a penalty for revealing information relative to product formulations and the Division should insist that security measures be observed throughout the registration process. The Public Health Service and the Department of the Interior have been advised of this provision in the Act.

The Task Force also noted that present space limitations preclude confidential discussions with representatives of industry. Immediate steps should be taken to set aside specific times and areas for this purpose.

5. Work Measurement

While records are being furnished to the Director's office relative to work received and completed, there has been no comprehensive work measurement system. We feel that work measurement is an essential and necessary part of good management and should be included in the Division's activities. It would provide for a distribution of work load, the number of items to be processed in relation to the

available personnel, permit a day-to-day analysis of backlog, and provide a basis for realistic budget requirements. The main objective, however, should be directed toward developing an efficient distribution of work load and to take advantage of maximum individual performance.

6. Criteria

The most important aspect of registering a pesticide chemical is the criteria used in determining safety and effectiveness. The Act and Regulations require that the registrant must provide data to support the registration and the Division must decide what criteria to use in accepting or rejecting the application. In reviewing this phase of registration, the Task Force found no written formal outline in any of the sections setting forth minimum requirements. While in many instances the judgments may have been good, they have nevertheless been much too arbitrary. Decisions have been made on the basis of personal knowledge possessed by the Section Head, but many of these have not been documented with adequate experimental data. Inspection of some documents has shown no appropriate information on translocation, persistence, fate, crop safety and only a very meager amount of toxicological data. The Division does not have a policy of requesting

new data in support of renewal applications, even though the published literature has indicated the need for further review. No real consideration has been given to massive treatment of certain soils or crops with pesticides which may cause injury to subsequent crops. The reason for this apparent lack of a critical review of all renewals as well as new applications has been attributed to a shortage of qualified scientific personnel trained to evaluate safety and effectiveness. We feel that it is more likely due to having no established set of requirements that must be met before registration can be granted.

In registering any economic poison as defined in the Act, the Pesticide Regulations Division must satisfy itself that registration and labeling provide for safety and efficacy. Requirements for toxicity data have recently been substantially increased and this aspect must be reviewed constantly to insure as full protection for the user and the public as is possible within the framework of the law. We strongly urge the development of basic requirements for establishment of safety and effectiveness for the various classes of compounds. This would permit all applicants to comply in a uniform way and would greatly curtail the need for personal interviews.

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There is also some confusion regarding the definition of terms. For example, when a material is registered for use at two pounds per acre, does this mean when applied uniformly or does it mean two pounds per acre of actual treated soil, which may, in fact, be only a small portion of the total crop area. Efforts should be made to relate the accepted quantities of pesticides to be applied to the methods of application.

7. Personnel

Over the past six years there has been a steady growth in the number of professional people employed in each of the Technical Evaluation Sections. Most of these people have received degrees in their respective disciplines except in Pharmacology where the training has been only ancillary to their major field. Because of the importance of pharmacology and toxicology in determining the safety of all products registered with the Department of Agriculture, we recommend that persons with advanced training in these disciplines be added to the Division.

We believe that the grade system is, in general, comparable to other regulatory divisions in the Agricultural Research Service,

although there may be some areas where the grade level is not compatible with the responsibilities of the position and may have been a deterrent to acquiring competent professional personnel. The time spent by each professional employee in his present grade averages 2.7 years, indicating that there has been a progressive promotion program in line with increased staffing. There is a wide range in age groups and it would appear that there are a number of persons in the 40-50 year age bracket who are potential candidates for more responsible positions. However, the mere promotion of people will not improve productivity or competence.

It was observed that throughout the Division there has been a general decline in morale, due largely to a pervasive lack of leadership, incentive, an aggressive training program, or encouragement to participate in scientific meetings. The functions and the administration of the Pesticides Regulation Division are not fully understood by those in responsible positions. Each section has its own interpretation of the Act and Regulations; there is a lack of communication between sections as well as within sections; and there is confusion regarding the policy toward advanced training. All of these have, in our opinion, contributed to the letdown in morale.

It is suggested that immediate steps be taken to: (a) define the mission and responsibilities of the Pesticides Regulation Division, particularly the authority to demand adequate evidence of safety and efficacy, and convey this to the staff; (b) institute a formal employee training and orientation program, including seminars; (c) improve communications between the various sections as well as with other departments; (d) clarify lines of authority within the Division.

Of particular concern to the Task Force was the lack of a formal recruitment program. The Division cannot possibly cope with the volume of work unless it makes a real effort to seek out competent people in the areas of greatest need.

D. Enforcement

1. Field Inspection

As of June 30, the Pesticides Regulation Division had sixteen inspectors covering 15 territories in the mainland of the United States. These territories vary in size from two to five states depending on the number of manufacturers in the area and the volume of pesticides used. The enforcement activities are divided into five principal functions: (a) collection of official samples by the inspectors; (b) laboratory

testing for compliance with the law and review of the results by the Technical Staff; (c) seizure actions based on laboratory and other testing; (d) handling of imports, and (e) cooperation with State regulatory agencies.

When samples have been collected by an inspector along with supporting information regarding interstate shipment, the samples are shipped to one of the five laboratories for analysis. The results are then forwarded to Washington for evaluation. If the sample is in accordance with the statement on the label, no further action is necessary. If the sample is in violation of the law, the lot may be seized and the shipper notified of his failure to comply with the law.

While there has been a steady increase over the past five years in the number of samples submitted and the number of seizures instituted, these samples represent only about four per cent of the total number of registered products. This program needs to be greatly accelerated and a goal of sampling ten per cent of all the products annually would not be unreasonable. This could be partially accomplished by reorganization and increased efficiency. In any event, the Division should examine the size and distribution of its inspection sample to make sure it is an adequate representation of all important components of the interstate pesticide trade.

We believe that the enforcement program must be strong if registration is to be meaningful. It should be the objective of the Division to have inspection in every State, thus giving credence to the claims made by the Department of Agriculture that it maintains surveillance over the products which "protect American food supply, health and property." There is, at present, no aggressive recruitment and training program for inspectors and the Division depends largely upon the availability of former FDA inspectors. Also, field and other enforcement personnel have been called upon to assist in registration. This only lessens the effectiveness of the enforcement program and is of limited benefit to registration. These conditions need to be corrected and a long-range planning program instituted.

2. Laboratories

While it was not possible for the Task Force to visit all of the laboratories associated with the Division's activities, we did receive reports on those at Corvallis, San Francisco, and New York and most of the members visited the laboratories at Beltsville. The general impression was that the chemical laboratories were well equipped with reasonably adequate space, but staffed by chemists who

lack leadership and knowledge of the mission of the Division.

The Task Force recognizes the importance of the chemistry laboratories to enforcement, but we are of the opinion that the regional or field laboratories should be consolidated into one central chemical laboratory. The necessity to expand each regional laboratory as the work load increases, along with duplication of equipment, makes them costly and inefficient. Each regional laboratory must have a capability of analyzing a wide variety of products since samples are submitted on a random basis and this requires an extremely versatile staff which is not likely to be found at the lower grades. We believe a central laboratory would allow for greater specialization at the lower grades and greatly facilitate the efforts of the enforcement branch to do a more effective job. Time and distance in transporting samples are no longer deterrents to a centralized facility if properly utilized.

In regard to the laboratories in Entomology, Animal Biology, Plant Biology, and Pharmacology, we can see no significant contribution of their activities in relation to the activities of the Division. In 1964, these laboratories tested several hundred samples but the results of these tests were not used in seizure actions. Samples submitted to the Bacteriology laboratory are tested for effectiveness and

are not referred to the Chemistry laboratory for analyses.

We recommend that the Division make a thorough evaluation of the need for these laboratories in relation to the overall mission of the Division and unless they can be made effective, they should be abandoned.

E. Proposed Changes in Organization

As our review of the procedures used in registration and enforcement progressed, it became increasingly evident that certain changes in organization are needed if the Pesticides Regulation Division is to meet its responsibilities in an efficient and orderly manner. We therefore propose the following changes and which are illustrated in the chart attached to this report.

1. An Advisory Staff selected from the various scientific disciplines, and any others the Director may appoint. The purpose of this Advisory Staff would be to assist the Director in establishing policy matters in the Division as well as in matters involving other Government agencies and industry. This staff would establish and review, on a continuing basis, the criteria to be used by the Registration and Enforcement Sections, including the development of a manual of internal procedures and a manual of instructions for industry. They would assist the Deputy

Director for Registration in resolving problems of registration arising from interagency review; assist the Deputy Director for Enforcement in case development, and assist the Office of Technical Data in assembling information.

2. An Office of Technical Data under the Director of the Division, to develop and maintain a modern information and retrieval system that would be useful to registration and enforcement activities. All personnel in the Division would assist in assembling technical data. Since much of the information would be of a proprietary nature, it will be necessary to develop control procedures.

3. An Administrative Officer who would be responsible for preparing the budget, developing a work measurement system, handle personnel matters, and assist in general housekeeping duties.

4. A Registration Branch under the supervision of a Deputy Director for Registration, who would be responsible for all aspects of registration including arrangement of conferences with industrial representatives. He would also seek the advice of the Advisory Staff in matters pertaining to interagency review.

The Registration Branch would include three sections:

(a) Registration Section - Receive and acknowledge all applications, assign file numbers, check them for completeness of information and route them to the appropriate sections for review. Maintain registration files for the Division with proper security control. Upon completion of review, assemble labels and appropriate information to be forwarded to Health, Education and Welfare and Interior with proper transmittal records. Notify the registrants of acceptance or rejection of applications, notify industry of registrations subject to renewal, and advise State regulatory officials when new pesticidal chemicals are registered.

(b) Renewal Section - This section would be staffed primarily by personnel from the present Technical Evaluation Sections and would be responsible for complete review of all renewal and routine applications.

(c) New Applications Section. This section would be staffed, in part, by personnel from the present Technical Evaluation Sections and would be responsible for all new and unusual applications, including the approval of use patterns, safety and efficacy, chemical nomenclature, precautionary labeling, residues, etc.

5. An Enforcement Branch under the supervision of a Deputy Director for Enforcement who would be responsible for all aspects of enforcement activities. This Branch would include:

(a) An Investigation Section responsible for collecting samples for laboratory testing and gathering related information for case development.

(b) A Case Development Section to evaluate and interpret reports and investigational data, make recommendations as to seizures, citations, and prosecutions, and prepare necessary reports and correspondence.

(c) A Laboratory Section. All laboratories would be under the direct supervision of a Chief of Laboratories. They would assay samples submitted by inspectors.

IV. Relation of Pesticides Regulation Division to Industry

Since the enactment of the Insecticide, Fungicide, and Rodenticide Act of 1947, numerous changes have been made in the Regulations affecting the registration of pesticide chemicals. Industry has been very responsive to these changes and the Division has, in turn, made every effort to allow industry a reasonable period of time to comply with the Regulations. The introduction of new chemicals and the necessity to review thousands of new labels has brought about a long delay in the registration process and the principal complaint of industry has been that the Division is not making a real effort to meet its responsibilities. As a consequence, industry has proposed, and we fully agree that: (a) a manual of instructions specifying the type of information needed for different classes of products would facilitate registration, (b) a standard format for submitting data would be of mutual benefit, (c) the registrant be notified of receipt of application and file number,

(d) the application be reviewed for completeness and the registrant notified immediately of any deficiencies, (e) a system be developed to prevent multiple requests for the same information, (f) security control be developed to protect confidential information.

While the Division may have been lax in developing methods to meet the increased demands, it must also be recognized that industry can and should do more to facilitate registration. There are many instances where applications have been poorly and improperly prepared with no supporting data for proposed changes in labeling. Every registrant should be required to supply whatever information is necessary for a proper evaluation of safety and no effort should be made toward registration until all information has been received. Approximately one half of all registrations are from companies associated with the Chemical Specialties Manufacturing Association or the National Agricultural Chemicals Association, and through experience, these organizations have been able to provide assistance to their member companies. However fifty to sixty per cent of the registrations come from unaffiliated companies.

V. Guidelines for Industry

At the present time there are not sufficient guidelines for industry to follow in submitting an application for review by the Pesticides Regulation Division other than what is described in the Regulations. Each registrant submits what has been suggested as a result of individual conferences or what he assumes to be necessary. What is sufficient for one group of compounds may not be sufficient for another. In evaluating a new herbicide, for instance, one would certainly want such information as toxicity, effectiveness, translocation, degradability, persistence, fate, use pattern, and crop safety. While it may be impossible to determine in advance all the information required to register a new chemical, it is possible to outline in principle, the kinds of data that would be essential to evaluate safety and effectiveness for phytotoxic and non-phytotoxic chemicals. Each compound or formulation, however, must be evaluated individually.

A manual of instructions outlining the basic requirements for each of the Sections in the Division would be most helpful and would greatly reduce the number of conferences required by industry representatives. It would provide more uniformity in applications and reduce the time

required for review. The manual should include a format for submitting information, samples of types of finished labels for different classes of compounds, number of copies required, forms to be used in submitting names of dealers, etc. The Division should also prepare a check list that could be sent to the registrant when further information is needed.

VI. Interagency Agreement

For many years the Director of the Pesticides Regulation Division maintained informal liaison between the Public Health Service, the Food and Drug Administration, and the Fish and Wildlife Service of the Department of the Interior. It was felt, however, that this informal liaison was not enough and the President's Science Advisory Committee recommended in its "Report on Use of Pesticides" that, in addition, decisions on registrations clearly relating to health should be reviewed by the Department of Health, Education and Welfare, and matters relating to fish and wildlife should be reviewed by the Department of the Interior.

In 1964, the Secretary of Agriculture, the Secretary of Health, Education and Welfare, and the Secretary of the Interior signed an ... departmental Agreement whereby the Department of Agriculture

would furnish to the other departments a listing of all proposals affecting registration and re-registration of pesticides and any additional information pertaining thereto. While the intent of this Agreement was to provide closer cooperation between the departments, its implementation has been hampered by a lack of cooperation and understanding regarding its true intent. The personnel of the Pesticides Regulation Division stated that the Public Health Service is responsible for the delay in registrations, and that the duplication of reviewing labels is unnecessary. They also feel that its record over the years is evidence that the Division is fully capable of evaluating the public health aspects. The Public Health Service representatives, on the other hand, informed the Task Force that USPHS should be responsible for registration of pesticides relating in any way to public health, that it has never taken more time to review the proposals than permitted in the Agreement, and that in many cases data are insufficient for approving the registration. There were numerous complaints from both agencies that can best be described as "picayunish," reflecting immaturity and irresponsibility. These complaints have been detrimental to the implementation of the Agreement. In contrast, the Fish and Wildlife Service and the Food and

Drug Administration have, in the opinion of the Task Force, shown evidence of good cooperation with the Department of Agriculture in the review of labels and in resolving areas of disagreement.

Some of the reasons for the apparent difficulties and delay in registration arising from the implementation of the Interagency Agreement are: (1) Comments and corrections made by the reviewers of applications in the Pesticides Regulation Division are not forwarded to Health, Education and Welfare and Interior. (2) There are no guidelines outlining specific areas of responsibility. As a result, the Public Health Service reviews the labels for spelling, chemical nomenclature, trade names, generic names, size of print, etc., which are functions delegated by law to the Department of Agriculture. (3) The provisions in the Agreement for settling differences between agencies simply have not been followed. Item (b) of the Agreement states that "if there is reason to question any of the items on the list, this will be communicated to the originating department within one week, stating the specific reason for need for further review." It was observed that, in many instances, the Public Health Service had not stated any reason but merely said more information was needed. As a matter of fact, the

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Public Health Service has taken upon itself, authority to obtain information from the manufacturer by direct correspondence, and this, we believe, is unwarranted. It has caused confusion and lack of confidence on the part of industry over the registration of pesticides. These areas of responsibility must be clearly defined by the representatives designated under the Agreement and issued in a memorandum of instructions. The Interagency Agreement itself, should be critically reviewed and perhaps revised.

The number of objections to registration that have not been resolved is of particular concern. Item (d) of the Agreement clearly states that "if one department concludes that the proposal should be rejected in whole or in part, this view shall be expressed in writing and shall be supported by appropriate scientific evidence. Upon being notified, the department responsible for final action will take the initiative to work out a basis for agreement." Our study revealed that the Public Health Service has, in most instances, failed to support its objections with scientific evidence. Unsupported personal opinion is not a valid basis for denial or cancellation of a registration. Unless the Department of Agriculture is provided with scientific

evidence to support objections, a basis of agreement cannot be found.

Item (e) of the Agreement provides that "in the event agreement is not reached among the department representatives within two weeks of the initial objection, the matter will then be referred directly to the Secretary of the Department responsible for final action with such information, views, and recommendations as the three department representatives deem appropriate." This has not been done. We fully support this provision of the Agreement and if adequate information is not made available by either of the two departments, the Secretary should proceed with "whatever administrative and scientific review procedures seem appropriate under the circumstances," as provided in Item (f).

The Task Force agrees with the statement in the recent report of the Pesticides Residue Committee of the National Academy of Sciences that the primary responsibility for registering pesticide chemicals should continue to be the responsibility of the U. S. Department of Agriculture and that other Federal agencies should serve in an advisory capacity.

VII. Guidelines for the Pesticides Regulation Division

After talking with each of the Section Heads regarding his responsibility in reviewing applications, it became apparent that there was a complete lack of instruction and procedure to be followed within the Division. As a result, each section is operating as an independent unit with its own ways of maintaining files and records and with no regard to the objectives of the Division.

We believe that detailed instructions must be developed, including flow charts on the steps required to complete a registration and indicating the relation of the individual sections to each other as well as to the overall mission of the Division. Each section should be cognizant of information being developed in other sections and a uniform system of handling such data should be developed and maintained for the benefit of the Division personnel. These requirements should be set forth by the Director as a part of a long-range planning program.

VIII. Relation of Pesticides Regulation Division to State and Local Governments

Section 13 of the Federal Insecticide, Fungicide and Rodenticide Act authorizes the Secretary to cooperate with any other department or agency of the Federal Government and with the official agricultural or

State regulatory agency of any State or subdivision thereof, in carrying out the provisions of this Act in securing uniformity of regulations. Following the passage of this Act, the State officials formed the American Association of Pesticide Control Officials to work with the Pesticides Regulation Division in developing Federal-State cooperative pesticide regulation programs.

It was thought that a joint cooperative program was necessary if adequate protection was to be provided the people in this country. It was generally agreed that the States would expect the Pesticides Regulation Division to assume primary responsibility for evaluating pesticide products for registration, set up guidelines, and generally provide information to the States which would enable each State to evaluate products registered within a State that were not subject to the Federal law on the same basis as they would be evaluated if they required Federal registration.

There have been regular meetings through the years of the Executive Committee of the Association of American Pesticide Control Officials with representatives of the Pesticides Regulation Division. These have been very helpful in enabling States to develop registration

programs, and in some cases States have required that a product be registered by the Pesticides Regulation Division before it would be accepted within a State. This cooperative program needs to be continued and strengthened.

In connection with enforcement, it was generally agreed that a cooperative program should be developed whereby analyses of pesticides made by the various State enforcement agencies would be reported to the Pesticides Regulation Division. It was hoped that this would give additional information to enable the Pesticides Regulation Division enforcement program to have opportunity to concentrate in those areas where more enforcement was needed and support the States rather than duplicate the work being done. Many States regularly provide information to the Division and those that are not doing so should be encouraged to support this effort. The Task Force believes that this should be a two-way street, and that in turn, the Pesticides Regulation Division should provide the individual States full information of its findings and results of its sampling in particular States.

In recent months there has been no follow-up of the information supplied by the States because of the backlog of registration work which

has interfered with the enforcement program. We strongly recommend that consideration be given to establishing an aggressive program to encourage full State participation and help in the enforcement program. This is particularly important as many States have pest control applicator laws in addition to labeling laws, and a close cooperative enforcement program can best serve to assure proper use of pesticides in accordance with the accepted labels.

Recommendations

As a result of the foregoing study, the Task Force makes the following recommendations:

1. The Agricultural Research Service should clarify the mission of the Pesticides Regulation Division and keep the Division personnel informed of the objectives.

2. The Director's Office should consist of a Deputy Director for Registration, a Deputy Director for Enforcement, an Administrative Officer, an Advisory Staff, and an Office of Technical Data.

3. Under the Deputy Director for Registration, establish a Registration Branch having three sections: (a) a Registration Section, (b) a Renewal Section, and (c) a New Applications Section, the latter two being composed of the present Technical Evaluation Sections.

4. Under the Deputy Director for Enforcement, establish an Enforcement Branch having three sections: (a) a Case Development Section, (b) an Investigation Section, and (c) a Laboratory Section.

5. The Division should publish a manual of instructions for use by the Division staff, outlining the general procedures for registration and enforcement and criteria to be used in evaluating safety and effectiveness.

6. The Division should publish a manual of instructions for use by industry outlining procedures for registration, types of finished labels and information needed for various classes of compounds.

7. There should be a periodic review of interpretations and the operating personnel should be advised of those changes.

8. The Division should insist on having a finished copy of the label to be used on the product before registration is granted.

9. The Division should make arrangements for space in which conferences with industry representatives can be held in privacy.

10. The Registration Section must exercise more rigid controls over the maintenance of files and of confidential information.

11. Requests to registrants for additional information in support of applications should be made by the Deputy Director for Registration.

12. Renewal notices should be limited to one notice thirty days prior to cancellation.

13. A work measurement system and long-range planning program should be instituted at once to identify future problems and to predict work load and needed resources.

14. The Division should establish, as soon as possible, an aggressive training and recruitment program. The employees should be encouraged to participate in the Incentives Awards Program.

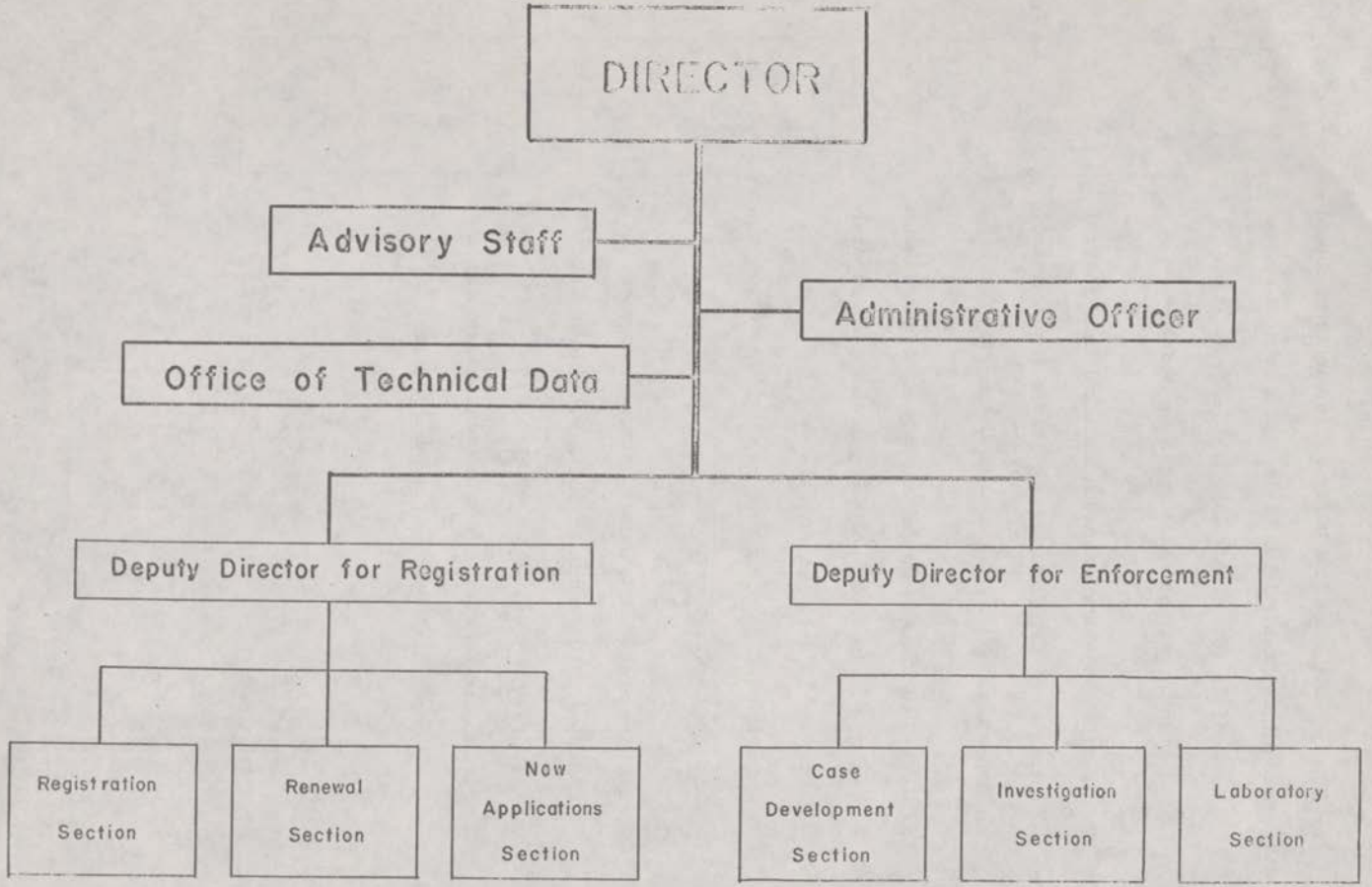
15. The Enforcement activities should be greatly accelerated and expanded.

16. The regional chemical laboratories should be consolidated into a central laboratory and a critical review made of the role of the biological laboratories in relation to their importance to the Division.

17. Greater cooperation between State and local governments would facilitate the work of the Enforcement Branch, especially in the area of sampling.

18. Representatives of the Interagency Agreement should recommend firm and specific guidelines of responsibility and authority in each of the participating Departments. The Agreement should be reviewed, and if necessary, revised.

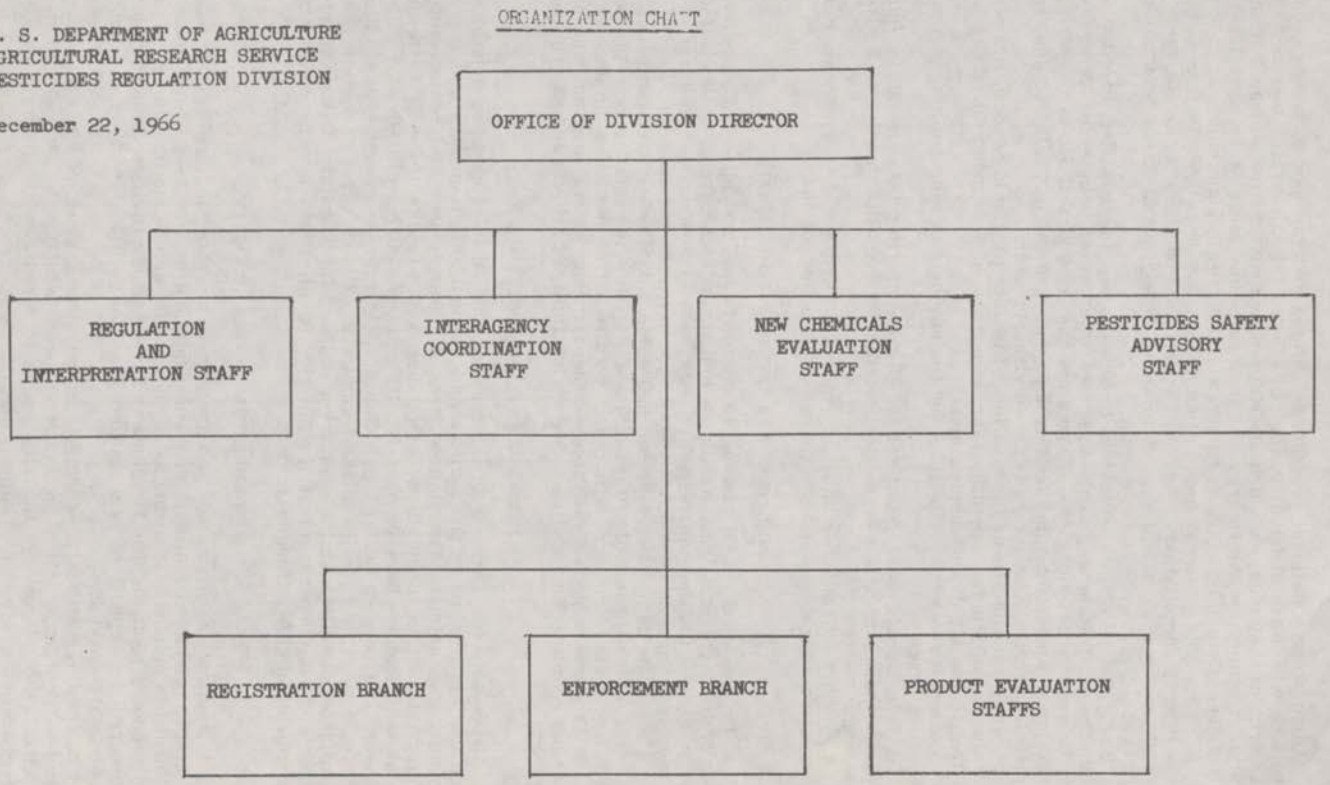
19. Because of the importance of pharmacology and toxicology in determining the safety of all products registered with the Department of Agriculture, we recommend that persons with advanced training in these disciplines be added to the Division.


DIRECTOR
Advisory Staff
Administrative Officer
Office of Technical Data
Deputy Director for Registration
Deputy Director for Enforcement
Registration Section
Renewal Section
New Applications Section
Case Development Section
Investigation Section
Laboratory Section

Appendix 7.—Organization Chart, Pesticides Regulation Division

U. S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE
PESTICIDES REGULATION DIVISION

December 22, 1966



OFFICE OF DIVISION DIRECTOR

Administers a national program to enforce Federal acts governing economic poisons which are distributed, sold, or offered for sale in any territory or the District of Columbia, or which are shipped or delivered for shipment from any State, territory, or the District of Columbia to any other State, territory or the District of Columbia, or which are received from any foreign country.

1. *Policy and program formulation.*—Recommends policies in line with, and assisting in formulation of, overall Department goals relating to control of economic poisons. Formulates programs and develops long-range program plans toward achievement of these goals.

2. *Program direction.*—Provides technical and administrative direction, coordination, and leadership in the execution of approved policies and programs.

3. *Cooperatve relationships.*—Represents the Agricultural Research Service in developing and maintaining relationships with Federal, State, foreign, public and private agencies in the conduct of the division program.

4. *Program analysis and evaluation.*—Provides for the inspection, review, and evaluation of program operations for the purpose of appraising the efficiency and effectiveness of policies and programs.

5. *Staff development.*—Provides for the development and training of the professional staff.

6. *Interdepartmental coordination.*—Represents the Department in interdepartmental coordination on matters relating to regulation, control, and usage of economic poisons.

7. *Studies.*—Conducts studies as required to carry out division responsibilities for determining safety and effectiveness of economic poisons.

REGULATION AND INTERPRETATION STAFF

1. *Program criteria.*—Develops, recommends, and provides staff assistance in promulgating regulations, standards, and procedures governing the marketing of pesticides and the enforcement of regulations. Provides staff assistance in the interpretation of division directives and directives of other agencies.

2. *Program data.*—Develops and maintains a data collection, storage, and retrieval system to provide to all division activities information essential to the efficient registration, inspection, and certificaton of pesticides products.

3. *Program appraisal.*—Evaluates the division control program and interagency coordination activities to ascertain validity of criteria and effectiveness of program.

INTERAGENCY COORDINATION STAFF

Represents the Division in interagency and other cooperative relationships on matters relating to the toxicity and residual effects on man and beneficial plants and animals. Determines areas of disagreement and recommends appropriate action to obtain understanding and expedite the flow of technical data and findings between agencies. Recommends changes in Division policy to insure full cooperation and compliance with interagency agreements. Participates with other agencies in the formulation of more effective agreements. Coordinates directly with the evaluation staffs of the Food and Drug Administration and the Department of the Interior on all Division registration actions requiring interdepartmental review.

NEW CHEMICALS EVALUATION STAFF

1. *Application.*—Examines and analyzes data supporting applications for registering products containing new chemicals and/or new uses of old chemicals. Furnishes opinion statements as to the amount of residue likely to result from a proposed pesticide use. Develops and recommends Division chemical analyses program in support of registration. Provides technical reviews of Division's chemical laboratories.

2. *Residue persistence.*—Conducts comparative analysis of reports of research and monitoring activities on registered patterns of use to determine if use results in illegal residue. Initiates action to terminate use pattern or product registration where studies indicate illegal residue.

3. *New/improved laboratory techniques.*—Analyzes internal and external techniques and technological developments to insure maximum effectiveness of the Division's chemical analysis activities. Insures publication of standard chemi-

cal analysis methodology incorporating latest techniques and to provide uniformity in Division chemical analysis and reports.

4. *Liaison.*—Provides liaison with related research efforts to promote application of research findings to division programs and facilitate conduct of division studies.

5. *Evaluation advice.*—Informs the product evaluation staff of new product and new use residue analyses and advises regarding decision of registration or noncompliance.

PESTICIDES SAFETY ADVISORY STAFF

1. *Pesticides safety.*—Conducts comparative analysis of reports of research and monitoring activities to determine the environmental effects on humans and nontarget plants and animals resulting from various use patterns, degrees of usage, and usage over extended periods.

2. *Precautionary labeling.*—Provides staff assistance and guidance in determining and developing the optimal size and wording, and use of precautionary labeling to protect humans and wildlife.

3. *Safety information.*—Replies to other ARS agencies and individual user inquiries concerning safety and hazards associated with the use of economic poisons.

4. *Studies.*—Recommends and develops Division toxicological studies as needed to support registration activities and toxicological evaluation procedures. Provides technical review of Division's toxicological laboratories.

5. *Safety advce.*—Informs the product evaluation staff of safety-hazard findings of product and use analyses and advises regarding decision of registration or noncompliance.

REGISTRATION BRANCH

1. *Program administration.*—Provides for the administrative routing of all registration and labeling applications to insure: numbering; acknowledgment; recommendation of review and evaluation; notification of findings to the applicant, HEW, Interior, State authorities, and appropriate Division activities.

2. *Correspondence.*—Prepares correspondence on applications, certifications, and registrations based on final determination made by the chief staff officers of the product evaluation staffs. Prepares notices of registration.

3. *Registration log.*—Monitors registration and label suspense files to insure timely notification of expiration and renewal dates. Reviews registrations for changes brought about by new findings which affect previously granted registrations. Compares new registration applications with existing registrations and notifies appropriate evaluation staff of any conflict.

ENFORCEMENT BRANCH

Plans, directs and coordinates with other Federal and State programs, field activities necessary to effectively regulate the marketing of economic poisons. This involves the following activities:

1. *Inspection.*—Collects official samples of registered products and conducts investigations of nonregistered products. Gathers all essential technical data and records and prepares statements of circumstances necessary when prosecution or notice of warning is warranted. Seizes or confiscates product when appropriate and supervises disposition of condemned products.

2. *Laboratory Services.*—Conducts chemical analyses and biological tests of all official samples taken from interstate shipments to determine if samples are effective when used as directed and are being marketed as represented at time of registration. Conducts laboratory tests to analyze, test, and evaluate formulations as requested by the product evaluation staff.

3. *Case development.*—Prepares case files on all alleged violations based on the investigational data, laboratory findings, and the opinions of the appropriate staffs. Determines the legal action appropriate and prepares citations. As required, certifies facts to U.S. attorney for prosecution and prepares notice of judgements.

PRODUCT EVALUATION STAFFS

Make final decisions, within the guidelines of the Division policy and criteria, concerning the approval of registration or notification of non-compliance of all economic poisons. Provide for the prompt and expeditious evaluation

of all applications for registration giving the highest priority to renewal applications. Conduct reviews of advisory committee findings and recommend the appropriate technical issuances with respect to registration of the produce. Review pesticides applications and certify as to the usefulness of a specific product. Coordinate with other chief staff officers of the Division and other agencies for opinions on product efficacy and safety within the staff assigned category of products.

Product evaluation staffs are established in the following groupings:

Disinfectants evaluation staff
Fungicides evaluation staff
Insecticides evaluation staff
Herbicides and plant growth regulators evaluation staff
Rodenticides evaluation staff

Appendix 8.—Examples of Objections Raised by the Public Health Service to Registration of Pesticides, With Comments by USDA and PHS Concerning Various Categories of Objections

The following information concerning various categories of objections made by the Public Health Service to registration of pesticide products was furnished by the Pesticides Regulation Division:

To obtain accurate figures as to the number of products which are being marketed to which the Public Health Service objected would necessitate an extensive review of records. We have listed examples of objection comments made by Public Health Service and have tabulated these on the attached table. It is noteworthy that the numbers have decreased over the years such that in fiscal year 1969 there were 185 registrations or reregistrations that appear to have been issued over Public Health Service's objections. This decrease is evidence that we have made use of many of their objections.

EXAMPLES OF OBJECTION COMMENTS MADE BY PHS

A. We cannot recommend registration of this registration number based on the fogging usage pattern as stated. We suggest that the label directions provide for a 2-hour time period following fogging before the room can be occupied.

B. We cannot recommend registration of the following registration numbers because they contain mercurials in concentrations for uses not approved in the memorandum of March 19, 1968, from Dr. Thomas H. Harris to Dr. Harry W. Hays.

C. We cannot recommend registration of this registration number based on the seed usage pattern until a dye is added to impart an unnatural color to the grain as a safety precaution against human consumption of the treated seed.

D. We cannot recommend registration of this registration number because the design and usage pattern provide for continuous vaporization of a pesticide in enclosed areas.

We would not object to registration of this product if the label bore the statement "Do not use in rooms continuously occupied by infants or infirm individuals."

E. We cannot recommend registration of the following registration number based on the home lawn usage pattern. Products containing chemicals sufficiently toxic to cause serious harm when a very small amount is consumed should not be stored or utilized around the home.

F. We cannot recommend registration of this registration number based on the type of bait used. Baits utilizing human foods create an undue hazard in the home environment especially to children.

G. We cannot recommend registration of the following registration numbers until additional toxicological data are available to more clearly establish the safety of this product. (This category also includes objection to registration due to lack of time to review data available, lack of a physical sample of the product and lack of data.)

H. We cannot recommend registration of this registration number because we do not believe that compounds which are carcinogens in experimental animals should be employed in pesticides.

I. We cannot recommend registration of the following registration number containing sodium fluoride as an active ingredient for use in the home because it does not contain a dye. Regulations for the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act state that a sodium fluoride product shall be uniformly colored blue or green.

J. We cannot recommend registration because the usage pattern calls for placing the product on squares of bread, which poses an undue hazard to children in and around the home.

K. As outlined in Dr. Daniel I. Mullally's letters of December 4, 1964, and May 18, 1965, concerning Naled (Phosphoric acid, 1,2-dibromo-2, 2-dichloroethyl

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dimethyl ester), we cannot grant approval to the following registration numbers:

L. We cannot grant approval of the following registration numbers containing Bromacil (Uracil, 5-bromo-3-sec-butyl-6-methyl-), as outlined in Dr. Daniel I. Mullally's letter of May 5, 1965, to Dr. Robert L. Jasper:

M. We are unable to grant approval to Registration Number ———— for the use of Vapona strips in closets or homes. We do not object to the use of this product in garbage cans and tight meter boxes.

N. As outlined in Dr. Daniel I. Mullally's letter of December 4, 1964, concerning Dibrom, we cannot grant approval to the following registration numbers:

O. We cannot grant approval for the following registration numbers because these applications make animal drug claims. It is our understanding that these products would fall under the purview of the Food and Drug Administration, and we suggest that you contact them.

	Fiscal year—				
	1965	1966	1967	1968	1969
A			9		6
B			223	95	63
C	9	84	73	57	28
D	7	22	31	19	28
E		126	146	53	32
F	1	5	16	11	4
G	85	140	12	2	5
H				9	18
I		18	12		1
J		4	7		
K	9	19			
L	15	11		1	
M	8	5			
N	27				
O	33	1			
Miscellaneous [1]	17	10	16		
Total	211	445	545	247	185

[1] Includes objection comments which were less prevalent than those listed above.

In addition to providing examples of objections made by PHS, the USDA Pesticides Regulation Division also made comments on the various categories of objections. The Division of Pesticide Registration, Food and Drug Administration (which now has the label review responsibilities formerly carried out by PHS) was given an opportunity to review and reply to the USDA comments. The following material prepared by the Food and Drug Administration lists the PHS objections, the USDA comments and the FDA response (identified as "PHS Reply"):

In validating the number of products for which registration was issued by USDA over the objection of Public Health Service for the fiscal of 1967, 1968, and 1969, we find that USDA has apparently issued more registrations over our objections than we objected to. Disregarding this small numerical disagreement, it is evident that USDA is registrating approximately 100 percent of the registrations objected to by PHS. USDA has not informed PHS as to why the objection was not acceptable.

USDA stated "it is noteworthy that the numbers (objections) have decreased over the years", but it is also noteworthy that the total number of registration applications submitted by USDA for review have also decreased over the years. Since, during the past year we only received approximately 60 percent of the registration applications which were accepted for registration by USDA, the remaining 40 percent could contain a high percentage of the various types of products which we object to. Thus the figure of 185 (USDA) is not valid in terms of total registrations for the fiscal year 1969.

It should also be pointed out that during fiscal year 1969, we made 5,052 suggested label changes.

Following is our reply to the comments made by USDA concerning various PHS objections.

A. PHS objections

We cannot recommend registration of this registration number based on the fogging usage pattern as stated. We suggest that the label directions provide for a 2-hour time period following fogging before the room can be occupied.

USDA comment

We have concurred with this objection on those products that we felt were warranted although Public Health Service did not submit scientific evidence.

PHS reply

The data submitted in support of registration was not sufficient to insure complete safety of humans on immediate occupancy of the treated area. Although USDA stated "we have concurred with this objection," registration was issued to every application we objected to.

B. PHS objection

We cannot recommend registration of the following registration numbers because they contain mercurials in concentrations for uses not approved in the memorandum of March 19, from Dr. Thomas H. Harris to Dr. Harry W. Hays.

USDA comment

We do not have scientific evidence to support cancellation of older registered products that fit this category. We have discussed this matter of mercurials with Dr. Prindle who agreed it was not necessary to cancel the registration of older products, but we agreed with Dr. Prindle that new products of this type should not be registered until additional toxicological data was submitted regarding the hazards of that particular product. Additionally, we requested Public Health Service to conduct epidemiological studies to determine the effect of mercury compounds in the environment of man.

PHS reply

Our policy is set forth in the aforementioned letter. See attachment No. 1.

(Attachment No. 1 is a March 19, 1968, letter from Thomas H. Harris, Chief of the Registration Section, pesticides program, PHS, to Dr. Harry W. Hays, director of the Pesticides Regulation Division, USDA. The letter makes the following statements:

"Upon consideration of the problem of continued registration of mercury compounds and their formulations, we are withdrawing our objections to certain of these compounds and their formulations, but are continuing our objections to other specified compounds and uses.

"Specifically, we withdraw our objections to phenylmercury formulations of less than 1-percent concentration for use as (*a*) paint, or other protectants, for wood or tile, including prepainted tiles; (*b*) fungicides for lawns, trees, or shrubs; and (*c*) fungicides for dust rags, dust mops, or other dust control preparations, including formulations of 0.1 percent or less on air filters or polyethylene sheeting.

"We withdraw our objections to medicinal statements containing ammoniated mercury, elementary mercury, and phenylmercuric compounds. It is only because these preparations are used for the control of ectoparasites that they fall under the Insecticide, Fungicide, and Rodenticide Act at all.

"We will continue to object to the use of any mercury compounds for the treatment of fabrics unless we can get real assurance that the fabric thus treated will never find its way into laundries where hospital linens and baby diapers are processed. Experience with pentachlorophenol indicated that such assurance is virtually impossible to obtain.

"Available information indicates that alkylmercury compounds are so dangerous that their use as pesticides should be prohibited. Therefore, we shall continue to object to the use of such compounds as ethylmercurithiosalicylic acid, methylmercury dicyandiamide, and methylmercury hydroxide at any concentrations for uses such as industrial water treatment, lawn treatment, dust control, or any other pesticide use.")

C. PHS objection

We cannot recommend registration of this registration number based on the seed usage pattern until a dye is added to impart an unnatural color to the grain as a safety precaution against human consumption of the treated seed.

USDA comment

The Federal Insecticide, Fungicide, and Rodenticide Act does not require a dye to be added to pesticide products used for treating seed. It does require that all seed that has been treated must bear a special warning "Treated seed—Do not use for feed, food or oil purposes." Certain products do not lend themselves to being dyed because the coloration is neutralized over a period of time due to incompatibility with other chemicals in the product. The Federal Seed Act does not require a dye to be added to seed treatment products although such treated seed must bear a warning statement that it has been treated. There is no single dye that will distinctively discolor all seeds. If a dye is to be used at the time of treating the seed, the color chosen must be based upon the kind of seed to be treated. The Federal Food, Drug and Cosmetic Act requires that all seed that is treated with a chemical must be denatured in a fashion that will prohibit its use for food or feed. It suggests such denaturing can be done by distinctly discoloring the seed with a dye; however, this is done at the time that the seed is treated by the incorporation of a dye at the seed treatment plant.

PHS reply

We concur that treated seed should be labeled as such and also be noticeable to the unaided eye. However, we believe a dye should be present in the pesticide formulation. This would reduce the chances of treated seed finding its way into the human food chain. This refers to all seed being treated, not just those at the seed treatment plants. One company voluntarily adds a dye to their products.

D. PHS objection

We cannot recommend registration of this registration number because the design and usage pattern provide for continuous vaporization of a pesticide in enclosed areas.

We would not object to registration of this product if the label bore the statement "Do not use in rooms continuously occupied by infants or infirm individuals."

USDA comment

The wording used by Public Health Service for this category is more a condition than on objection. Sometime ago we agreed with Public Health Service on the required precautionary statement and have been calling for it routinely on this type of product. We transmit labels to Public Health Service simultaneous with starting our own review and therefore, Public Health Service does not have the benefit of knowing our review has required this precautionary statement.

PHS reply

We will continue to make this objection if the labels are received without the required caution statement. However, this problem appears to have now been settled.

E. PHS objection

We cannot recommend registration of the following registration number based on the home lawn usage pattern. Products containing chemicals sufficiently toxic to cause serious harm when a very small amount is consumed should not be stored or utilized around the home.

USDA comment

This objection by Public Health Service is inconsistent with the Hazardous Substances Act which permits concentrates to be stored or used around the home provided that they bear adequate precautionary statements; for example, household ammonia, chlorine products, lye, etc.

PHS reply

The recommendations of this division are not governed by the Hazardous Substances Act. It is our opinion that when you reduce or eliminate the hazardous economic poisons in the home, you reduce hazards.

F. FDA objection

We cannot recommend registration of this registration number based on the type of bait used. Baits utilizing human foods create an undue hazard in the home environment especially to children.

USDA comment

We have concurred with Public Health Service on this objection. We consider any material attractive to children to be a potential hazard and we appreciate Public Health Service calling this to our attention. We require that baits containing human foods be of such physical state or color that they are no longer recognizable as food material. Additionally, the label must bear a statement that baits must be placed only in areas inaccessible to children and pets.

PHS reply

During the fiscal year 1969, PHS objected to the registration of only four applications in this area. If USDA concurs with the PHS objection, as stated in their comment, why were all four applications registered over PHS objection? Attached please find a photocopy of these registration applications. See attachment No. V.

(Attachment No. V is in the subcommittee files. It consists of material relating to proposed registration of Paket Brand Poison Peanuts Gopher & Mole Killer, Hub States "Antu" Rat Poison, J. J. Dill Co. Pelleted Poison Peanuts, and Sperry's Poison Peanuts.)

G. PHS objection

We cannot recommend registration of the following registration number until additional toxicological data are available to more clearly establish the safety of this product.

USDA comment

We have concurred with this objection. Note from the table that the number has decreased significantly over the years for this objection.

PHS reply

During the fiscal year 1969, PHS objected to the registration of only five applications in this area. If USDA concurs with the PHS objection, as stated in their comment, why were all five applications registered over PHS objection? Attached please find a photocopy of these registration applications. See attachment No. VI.

(Attachment No. VI is in the subcommittee files. It consists of material relating to proposed registration of zinc fluosilicate and sodium arsenate for use in mothproofing fabrics and various insecticide combinations to be sprayed in food handling areas.)

H. PHS objection

We cannot recommend registration of this registration number because we do not believe that compounds which are carcinogens in experimental animals should be employed in pesticides.

USDA comment

There is no supporting evidence for this objection. The Delaney clause to which Public Health Service is probably referring is not applicable because it refers to residues on food and therefore to oral ingestion of the chemical. A chemical that is a carcinogen by oral ingestion does not necessarily mean it is a carcinogen by inhalation or skin contact. Studies are being conducted by several routes of administration. There is no evidence of a carcinogenic effect from a single exposure or even short intermittent exposures. Most carcinogenic studies are based on continuous exposure over long periods of time.

PHS reply

It is our opinion that the general public should not be exposed to a chemical known to be a carcinogen when equally effective noncarcinogenic chemicals are available. We are hesitant to state that a chemical which causes cancer only on chronic exposure in rodents will not cause cancer in humans even after occasional contacts.

I. PHS objection

We cannot recommend registration of the following registration number containing sodium fluoride as an active ingredient for use in the home because it does not contain a dye. Regulation for the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act state that a sodium fluoride product shall be uniformly colored blue or green.

USDA comment

We concur with this objection. This is another instance where Public Health Service did not know at the time of their review that we had already established that the product had been discolored.

PHS reply

We shall continue to make this objection until we are notified of the change.

J. PHS objection

We cannot recommend registration because the usage pattern calls for placing the product on squares of bread, which poses an undue hazard to children in and around the home.

USDA comment

This is an extension of objection "F."

PHS reply

See item F.

K. PHS objection

As outlined in Dr. Daniel I. Mullally's letter of December 4, 1964, and May 18, 1965, concerning Naled (Phosphoric acid, 1,2-dibromo-2, 2-dichloroethyl dimethyl ester), we cannot grant approval to the following registration numbers.

USDA comment

We have apparently satisfied Public Health Service. It would appear from table 1 that previous objections have now been resolved.

PHS reply

This objection was based on the inadequate data supplied by USDA. See attachment No. II.

(Attachment No. II, the December 4, 1964, letter from Dr. Mullally, Medical Officer, Office of Pesticides, PHS, to Dr. R. J. Anderson, Deputy Administrator, Agricultural Research Service, is in the subcommittee files. The letter reviews various alleged deficiencies in studies submitted and makes the following statement:

"In summary, most of the studies submitted lack any semblance of scientific rigor. In addition, chronic animal studies are lacking, observations on the health of occupational workers are not reported, and there are no laboratory experiments on higher mammals. Furthermore, there are no reproductive studies.

"The studies submitted are incomplete, unsophisticated, and unsatisfactory. * * *")

L. PHS objection

We cannot grant approval of the following registration numbers containing Bromacil (Uracil, 5-bromo-3-sec-butyl-6-methyl-), as outlined in Dr. Daniel I. Mullally's letter of May 5, 1965, to Dr. Robert L. Jasper.

USDA comment

We have apparently satisfied Public Health Service. It would appear from table 1 that previous objections have now been resolved.

PHS reply

This objection was based on the inadequate data supplied by USDA. See attachment No. III.

(Attachment No. III, the May 5, 1965, letter from Dr. Mullally to Dr. Jasper, assistant chief of staff officer, Pharmacology, Pesticides Regulations Division, is in the subcommittee files. It lists four additional types of studies considered by PHS to be necessary to complete its appraisal of Bromacil.)

M. PHS objection

We are unable to grant approval to registration No. —— for the use of Vapona strips in closets or homes. We do not object to the use of this product in garbage cans and tight meter boxes.

USDA comment

We have apparently satisfied Public Health Service. It would appear from table 1 that previous objections have now been resolved.

PHS reply

This objection has now been resolved.

N. PHS objection

As outlined in Dr. Daniel I. Mullally's letter of December 4, 1964, concerning Dibrom, we cannot grant approval to the following registration numbers.

USDA comment

We have apparently satisfied Public Health Service. It would appear from table 1 that previous objections have now been resolved.

PHS reply

This objection was based on the inadequate data supplied by USDA. See attachment No. IV.

(Attachment No. IV, a May 18, 1965, letter from Dr. Mullally to Dr. Jasper, is in the subcommittee files. It lists three categories of additional data considered necessary for PHS to complete its evaluation of Dibrom.)

O. PHS objection

We cannot grant approval for the following registration numbers because these applications make animal drug claims. It is our understanding that these products would fall under the purview of the Food and Drug Administration, and we suggest that you contact them.

USDA comment

We have apparently satisfied Public Health Service. It would appear from table 1 that previous objections have now been resolved.

PHS reply

The applications are now forwarded by us directly to Veterinary Medicine (FDA).

Appendix 9.—Brief on Shell Chemical Co.'s Position Regarding the Safety of No-Pest Strip ® Insecticide

(The following statement was submitted by the Shell Oil Co. with a request that it be included in the hearing record)

A review of the transcript of the hearings before the House of Representatives' Subcommittee on Intergovernmental Relations of May 7 and June 24, 1969, makes it imperative that Shell Chemical Co. supply more complete details regarding the registration of the No-Pest® Strip Insecticide, to clarify the issue on the data available for human and food safety evaluation and to establish the significance of this evaluation in reference to competitive products.

The comments made by personnel of both the U.S. Department of Health, Education, and Welfare (USDHEW) and the U.S. Department of Agriculture (USDA) failed to bring to the committee's attention that the above-named product was registered (1963, see exhibit No. 1) prior to the establishment of a formal interdepartmental review of pesticide safety (see lines 24, 25, page 770; lines 15, 16, page 771 of Transcript of Proceedings of June 24, 1969). Further, it should have come to the committee's attention that there had already been a concurrence in the acceptability of this product for home use on the part of the U.S. Public Health Service, Toxicology Section, Communicable Disease Center, Atlanta, Ga., also prior to the formation of the interdepartmental review groups. We assume that the USDA files include documents on this point.

At the time Shell presented a label for registration of Vapona® Resin Strips (synonymous with No-Pest® Strips) to the U.S. Department of Agriculture, the U.S. Public Health Service (USPHS) had already conducted studies on human safety in the Upper Volta, Nigeria, and in the United States, which were used in part to establish the safety of the product. Shell was advised of the use of these studies by the USDA. The USPHS studies included trials with a vapor generator utilizing a wax formulation developed by USPHS rather than the current resin formulation; however, the principle of continuous generation was the same for both. Copies of the USPHS published reports are appended (see exhibit No. 2). In Shell's original negotiations with the USDA, regarding the label for Vapona Resin Strips, it was pointed out by USDA that most of the data on human safety had been produced outside the United States and they advised Shell to obtain more data on use of Vapona© Resin Strip specifically under conditions more nearly consistent with those likely to occur in this country.

On the basis of the above advice, Shell instituted the first of a series of studies which we now refer to as "Arizona-type" studies (see exhibit No. 3). The data developed from these studies confirmed that prolonged exposure of people under conditions of use as directed on the label would not cause any effects on the health or well-being of U.S. populations exposed to Vapona. In this first study, seven families were exposed for a period of 1 year either to a blank strip or the actual product as marketed. The strips were installed in every room in each house at a rate of one strip per thousand cubic feet of space. In addition, Vapona "Mini-strips" (2 inches long) were installed in each closet. All strips were replaced every 3 months and extensive clinical observations were made on each occupant of the homes involved in the study. These clinical tests included routine determinations of blood plasma and red cell cholinesterase activities and hemoglobin, hematocrit, reticulocyte and platelet determinations. The researchers concluded that there had been no change in the cholinesterase values of the exposed population as compared to the control population and no effect in any of the people involved in the study.

The study has recently been repeated with 16 families (approximately 80 people) in the same area for a period of 6 months. In this particular study, the strips were replaced once every month. Again, the entire house was treated: bedrooms, living rooms, dining rooms, and kitchen areas. The study included both air-conditioned homes and air-cooled homes, and 3 months of the study covered essentially closed conditions likely to be encountered during the cooler months.

These studies are in the process of being reported at this time. A verbal report from the researchers indicates that there has been no effect on the health of the individuals involved.

Medical researchers, believing on the basis of data available that no risk to health would result, have exposed the more sensitive segments of the population (infants and the infirm) to No-Pest® Strip. In two basic reports (see exhibit No. 4), one from Italy and one from Japan, researchers have concluded that there is no effect on the health of such individuals. In the Italian study, changes in plasma (or pseudo) cholinesterase levels did not occur in most instances except under stringent conditions of exposure and these are in fact so slight that it is doubtful as to their significance. There were no detectable changes in the acetyl (or true) cholinesterase in any patient studied. Patients with liver disease did show evidence of depression of plasma cholinesterase. Similar observations were recorded in the Japanese study. This change is not sufficient to suggest any risk to health, particularly in view of the fact that there was no change in the acetyl (red blood cell) cholinesterase levels. These studies have been reported to both the USPHS and the USDA.

The studies in Italy, under the direction of Professor Vigliani, have been continued particularly with reference to newborn infants and new data from these studies have just been received by Shell. The conclusions are that there is no effect on the health of either the newborn infants or their mothers. A copy of this report is appended. (See exhibit No. 5.)

This brings us to the point of comparing the status of the safety of No-Pest Strip with those household insecticide products that might be used in lieu of or in competition with our product by the public at large. On the basis of a general review of the published literature, we believe that the total data regarding Vapona Resin Strip generators, with reference to human populations, exceed that published or known on any other household pesticide. The human safety evaluations have been made by researchers in a broad global distribution and include work from governmental agencies, such as the USPHS.

The USPHS has expressed its viewpoint regarding household insectcides. The National Pest Control Association Technical Release No. 1–69 comments specifically on PHS attitudes regarding the exposure of people continuously to any pesticide (copy of release attached, see exhibit No. 6).

In our discussions with the USDA regarding the added precautionary statement, we pointed out that we felt Shell was being discriminated against because we were being asked to apply to our product a precautionary statement which all the evidence available indicated to be unnecessary.

We would like to comment that we discussed with the USPHS acceptable precautionary statements in light of their experience in dealing with the public health and the use of household insecticides. We then voluntarily went to the USDA after having reached some agreement with USPHS through our medical consultant, Dr. Mitchell Zavon, on this matter (see exhibit No. 7). The statement agreed to by the USPHS was as follows: "Do Not Use in Rooms Continuously Occupied by Infants and Infirm Individuals." Attached is a copy of the letter of February 8, 1968, from Dr. S. W. Simmons of the USPHS to Dr. Zavon (see exhibit No. 8) giving his views on this subject.

The USDA ultimately refused to accept this exact statement and insisted on deleting the word "Continuously," thereby, in our opinion, making the statement unnecessarily stringent. It was during this period of technical debate that we presented the newly accumulated evidence on human safety, all of which showed essentially negative responses with regard to infants and the infirm. Data have also been published by the World Health Organization indicating that in one series of studies, 10,000 people in one community and 25,000 people in another community were exposed to Vapona generators for 2 and 4 years respectively without regard to conditions of health or age of the inhabitants. The USPHS researchers concluded that there were no effects on the health of the individuals exposed in this study. Nowhere in these reports do we find any indication that the infirm or infants should not be exposed, nor in fact would the data support such a conclusion (see exhibit No. 9). However, having finally lost all hope of convincing Dr. Harry W. Hays of the USDA of the technical justification of our position and being unable to delay any longer the manufacture and packaging of our 1969 requirements, we acceded to his demands and added the more stringent precautionary statement which has appeared on the label of all product produced since autumn 1968. Production was resumed in February 1969, after agreement on the new label.

Mr. James R. Naughton, the counsel for the subcommittee, also reviewed the significance of Vapona residues in food (transcript of committee proceedings, June 24, 1969, lines 7–25, p. 794; lines 1–25, p. 795; lines 1–20, p. 796). In this regard there are two important factors to bear in mind. First, the Arizona studies, contracted for by Shell with outside researchers, included the ingestion of foods that would be exposed under normal household condition to the vapors of the No-Pest Strips. While the people living in the test homes were exposed to Vapona from the air, they were also ingesting any Vapona residues which would have been absorbed by their foods. In view of the remarkably negative reaction of the human subjects exposed under these condtions, it appears to be an academic problem to dwell upon what might occur from insignificant Vapona residues on foods. We believe that the subcommittee members, and others who have questioned the safety of this product, may have overlooked the fact that most of our evaluations on No-Pest Strips have involved human exposure.

The second point regarding food safety pertains to the role of the Food and Drug Administration in establishing food tolerances for dichlorvos. To date, tolerances of two parts per million have been set for high-fat content (6 per cent or over) foods and 0.5 parts per million for low-fat content (under 6 percent) foods. In addition, tolerances have also been set on several raw agricultural commodities. In FDA's evaluation, they used (as is customary) extensive animal data including 2-year feeding studies on rats and dogs as well as reproductive studies extending for three generations in rats. These tolerances far exceed any residues likely to occur in foods in homes or restaurants where No-Pest Strips are used as directed.

We would like to point out that a review of the President's Science Advisory Committee Report on Pesticides (1963) clearly indicates that Vapona fits all of the desirable characteristics of a pesticide to be used in man's environment. In this instance, Shell has taken a product which is relatively toxic acutely and contained it in such a way as to make it one of the least toxic materials acceptable for use in the home.

Its chemical stability is such that if it were somewhat less stable, it might be cast aside as a useless insecticide. In terms of human health, the material is extremely rapidly metabolized and excreted, thus producing no residues in tissues and no adverse effects on health. Furthermore, because of its properties and characteristics, residues of it will not build up in the environment.

As a final comment concerning the safety of the No-Pest Strip, it is quite obvious from the examination of the vital statistics on accidental insecticide poisonings, particularly with reference to the ingestion of solid and liquid substances, children consume almost anything and everything found in the home and, unfortunately, in some cases such ingestions are fatal. Again, with reference to the particular and unusual characteristics of this pesticide product, we feel quite confident that, though attempts may be made by children to ingest No-Pest Strips, all of us can rest easy knowing that there will be no effect on the health of the child, let alone any fatality of infants, and certainly no deaths in such attempts at ingestion. Data which we have submitted to the Federal agencies show that it is virtually impossible for any person or animal to ingest or extract a lethal amount of dichlorvos (Vapona) from a No-Pest Strip. It is not generally known that the dichlorvos serves as a plasticizer for the resin used in this product which accounts for its release at a safe, slow rate. It is this feature which has made it invaluable as a household insecticide and as an anthelmintic drug for animals and the most promising anthelmintic for humans on the horizon. Also, it is this feature which cast suspicion on the safety of the product manufactured by the Aeroseal Corp., which was referred to during the hearings. It was impossible for the dichlorvos to serve as a plasticizer in the porous paper strips used in Aeroseal's product, thus allowing the possibility of ingesting lethal amounts of dichlorvos by sucking, chewing, et cetera. We feel that we have a moral obligation to intervene in attempts to market unsafe formulations of our chemical dichlorvos in order to protect both the public and the reputation of this insecticide.

It may also be of interest to know that dichlorvos has recently been adopted as the insecticide of choice for disinfection of international aircraft. The research and development work was done by the USPHS over a period of years. The acceptance for this use is significant because it further attests to the safety of dichlorvos to both the passengers and the aircraft crews exposed to its vapors.

We sincerely believe that all pesticide chemical companies should be encouraged to formulate and offer to the public products that meet the high standard which we believe our product establishes.

(NOTE.—The exhibits referred to are in the subcommittee files.)

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